Health Canada Santé Canada

A Fresh Start:
Final Report of the ONHP Transition Team

Presented to
The Honourable Allan Rock, PC, MP
Minister of Health
Government of Canada

Presented by
The Transition Team
Office of Natural Health Products

March 31, 2000

Canada

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Executive Summary

On March 26, 1999, the Minister of Health, the Honourable Allan Rock, announced the Government's acceptance of all 53 recommendations made by the Standing Committee on Health in its 1998 report on natural health products.[1] In accordance with the Standing Committee's report, the Minister acted to initiate the creation of a new Office of Natural Health Products (ONHP) under the direction of the Assistant Deputy Minister, Health Protection Branch. In addition, the Minister announced the creation of an ONHP Transition Team to ensure an appropriate process to build public confidence in a new approach to the regulation of natural health products (NHPs).

The mandate of the ONHP Transition Team was to structure an administrative and regulatory framework and identify broad policy directions to assist Health Canada in implementing the 53 recommendations made by the Standing Committee on Health in its landmark report.

Since its inception, the Team has made substantive progress in conceptualizing and delineating an operational framework for the newly created office. During the process, the Team moved forward on a number of fronts. The task has been both provocative and rewarding. Throughout the process, the Team has been guided by the 53 recommendations as presented by the Parliamentary Standing Committee on Health and accepted by the Government.

The following recommendations are the embodiment of almost ten months of creative effort of the ONHP Transition Team, submitted for the Minister's consideration. They lay the foundation for a fresh start in the regulation of natural health products in Canada. Hopefully, they also will act as a catalyst in helping to move Canada toward a more pro-active, holistic health care paradigm.

Creating the Vision

1. **Mission Statement:** The mission of the Office of Natural Health Products is to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

2. **Vision Statement:** The new Office of Natural Health Products shall be:

    a) acknowledged as the national authority for the regulation of natural health products used in Canada;
    b) recognized worldwide as a leader in natural health product regulation;
    c) a leading national and international partner in the management of natural health products; and,

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[1] *Natural Health Products: A New Vision*. Report of the Standing Committee on Health, November 1998.

d) the vehicle for Health Canada to create and maintain an innovative regulatory environment, based on a wellness model that will set a global standard in natural health product regulation.

Organizational Structure

3. **Organizational Structure:** The organizational structure of the ONHP, including the Executive Director, Director of Policy and Regulatory Affairs, Director of Research and Development, Director of Outreach and Communications, and Director of Product Regulation, as outlined in Sections 2.1 to 2.5 of the report, be accepted as proposed.

4. **Field Inspectors:** The ONHP should ensure that field inspectors carrying out the duties of the Office are trained and knowledgeable about NHPs and that inspection duties are performed consistently and on a regular basis to ensure uniform enforcement of regulations across the country.

5. **Expert Advisory Committee:** The mandate and structure of the Expert Advisory Committee (EAC), as outlined in Section 2.6 of the report, be accepted as proposed.

6. **Transition Advisory Team:** A sub-group of four to five ONHP Transition Team members, with a quorum being three members, should be retained on an interim basis to serve as a Transition Advisory Team (TAT). The TAT should be assembled at the call of, and report to, the Executive Director. The TAT should provide ongoing advice and counsel to help ensure that the vision and intent of the Standing Committee and ONHP Transition Team recommendations continue to be reflected in the new Office and operational framework. While travel and accommodation expenses should be paid, members should not receive any remuneration for their counsel.

7. **Ongoing Consumer Representation:** Upon the winding down of the TAT, the Executive Director should ensure that a consumer representative, having strong knowledge in and experience with NHPs, be appointed to the EAC.

8. **Management of NHPs within HPB:** The Assistant Deputy Minister, Health Protection Branch (HPB), should:

    a) play a strong role in coordinating the policy and regulatory activities of the Branch's various regulatory units with respect to NHPs;
    b) ensure that such policy and regulatory activities do not result in duplication and/or inconsistent regulation; and,
    c) immediately begin to coordinate regulatory activities based on the leadership provided by the ONHP.

9. **Interim Management Strategy:** In the interim and until such time as the regulatory framework is fully implemented, Health Protection Branch (HPB) immediately implement an Interim Management Policy for the current regulation of NHPs. This policy should include the following:

a) the ONHP Executive Director should be the level of interim management contact and decision making;
b) all matters of regulatory action on NHPs (or those products deemed NHPs under the ONHP's working definition) proposed by any HPB Directorate or other branch of Health Canada should be undertaken through the ONHP; and,
c) all regulatory decisions and actions should be conducted in an open manner and reported with full explanatory communications to all stakeholders and the Canadian public in a timely fashion.

Regulatory Framework

10. **Working Definition of a Natural Health Product:** The ONHP and Health Canada should work toward appropriate legislative or regulatory change to ensure that the legal interpretation of natural health products (NHPs) clearly differentiates these products from foods and pharmaceuticals.

11. **Site Licensing:** The specified criteria deemed essential for an effective ONHP site licensing program, as outlined in Section 3.2.1 of the report, be adopted as proposed.

12. **Importation for Personal Use:** The ONHP, in conjunction with Health Canada's Legislative Renewal Initiative, develop a regulatory provision which clarifies the reasonable grounds respecting the importation of NHPs for personal use.

13. **Product Licensing – Guiding Principles:** The Guiding Principles for developing a product licensing system, as outlined in Section 3.2.2(a) of this report, be adopted as proposed.

14. **Product Licensing – Establishing Safety, Quality and Claim:** The ONHP should adopt a process for product licensing which relies on two basic methods for establishing the safety, quality and claim of products:

    a) the use of available evidence, including non-attestable monographs, on a product-by-product review and assessment process; and,
    b) the use of ONHP-approved attestable monographs against which lower risk product applications can be audited.

15. **Product Licensing – Monographs:** Monographs should be subject to a process of regular review, update, revision and assessment of risk.

16. **Lower Risk Products with Attestable Monographs:** The ONHP should adopt an approach to optimizing the use of ONHP-approved attestable monographs which has, as its initial approach, a pre-market audit process with a 45 calendar day limit on government response to the application.

17. **Lower Risk Products – Post-Market Notification Trial Project:** Within three years of the coming into force of the new regulations, the ONHP should move to further optimize the monograph system. Specifically, a trial project utilizing a post-marketing notification

approach to product registration should be implemented and evaluated for a limited number of ONHP-approved attestable monographs. If successful, the ONHP could further expand the use of such a post-market system.

18. **Lower Risk Products without Attestable Monographs:** For lower risk products without ONHP-approved attestable monographs, the provision of acceptable evidence, consistent with the margin of safety of the product, should be required for assessment of the product by ONHP.

19. **Higher Risk Products:** For higher risk products, performance standards for the review and assessment of submissions should be set in consultation with stakeholders.

20. **Cancellation of Product License:** The conditions under which the Executive Director may cancel licenses need to be set out in regulations. Product recall, product seizure and other compliance activities should be available to the Director and subject to a timely appeal process by the marketer.

21. **Public Registry:** A public registry of all ONHP registered products, that is easily accessible by the public and stakeholders, should be established; the registry should include the product name, active ingredients, registration number and company name for each product.

22. **Electronic Submissions:** An electronic submission system should be established for all product reviews, and in the case of products for which there is an ONHP-approved attestable monograph, an electronic submission and review system for abbreviated assessments (or audits) should be developed.

23. **Good Manufacturing Processes:** The ONHP begin consultation with manufacturers, packagers and importers to develop the specific regulatory requirements and guidelines for good manufacturing practices (GMPs) of natural health products, which will assist inspection and compliance to GMP regulations.

24. **Standards of Evidence:**

    a) The evidence to support the safety and claim of a product must not be limited to double blind clinical trials, but may also include other types of evidence, such as generally accepted and traditional references, published monographs, expert opinion reports, other types of clinical trials and other clinical or scientific evidence;
    b) the ONHP, with the assistance of the EAC, should establish a list of acceptable references, develop the criteria for ONHP-approved monographs and develop criteria for linking levels of evidence to health claim validity; and,
    c) claim approval by the ONHP, on the basis of scientific evidence, should be allowed to be applied to other products, with supportive scientific evidence of at least an equal level of claim assessment.

25. **Administrative Lists:** The ONHP develop an administrative list of NHP categories based on the proposed working definition. The list should include broad categories of products, such as those set out in the working definition, and there should be flexibility in the

inclusion of products in the list and a means to amend such a list. Monographs for products which fall into these categories and which meet the criteria developed for monographs used in audit applications should be adopted by reference to other standards.

26. **Determination of Risk:** The specified factors deemed essential for an effective determination of risk, as outlined in Section 3.2.5(e) of this report, be adopted as proposed.

27. **Post-Market Monitoring:** The specified criteria deemed essential for an effective post-market monitoring program, as outlined in Section 3.2.5(f) of the report, be adopted as proposed.

28. **Product Labelling:** The specified criteria deemed essential for an effective labelling program, as outlined in Section 3.2.6 of the report, be adopted as proposed.

29. **Product Labelling – Standing Committee Recommendations:** The ONHP develop the policy framework to address the spirit and intent of recommendations 23 and 24 of the Standing Committee's report.

30. **Penalties for Non-Compliance:** The specified criteria deemed essential for an effective, yet reasonable, program of compliance, as outlined in Section 3.2.7 of the report, be adopted as proposed.

31. **Cost Recovery:** Fees imposed by the ONHP should adhere to cost recovery and charging policy guidelines, adopted April 1997, by the federal Treasury Board. In establishing such fees the ONHP should undertake meaningful consultations with clients to ensure that those who must pay for the service have a voice in the design and delivery of such service. The aim of consultations should be to avoid the imposition of unfair or unreasonable cost burdens on clients, while ensuring necessary rigour in the licensing and regulatory process. Any fees imposed should be directly related to, and reflect fairly, the cost of service and should be subject to proper impact assessments.

32. **Appeals Mechanism:** The Appeals Mechanism, including the structure of the Appeals Committee, proposals for cost recovery, use of expert advisors, time frame for review, formulation of a guidance document and proposals for consistency of application, as outlined in Section 3.3 of the report, be adopted as proposed.

Modifications to Current Regulations

33. **Vitamins, Minerals and Amino Acids:** Divisions 4 and 5, Part D of the Food and Drug Regulations should be repealed and replaced by the NHP regulatory framework.

34. **Schedule F:** Changes to Schedule F should continue to follow the current administrative processes to ensure adequate consultation where required; however, the need for gazetting in addition to this process should be removed. Schedules should become administrative lists and scheduled products should have their conditions of sale attached to their product licenses

35. **Division 8:** Division 8 should be amended to reflect a relative-risk product licensing system, as well as the cultural, philosophical and historical context of product usage.

36. **Section 3 and Schedule A:** Section 30(1) of the Food and Drugs Act should be invoked to remove all diseases listed in Schedule A; Sections 3(1) and 3(2) should be revoked through the Legislative Renewal Initiative.

37. **Sampling:** Current sampling restrictions should be removed from the Food and Drugs Act through the HPB Legislative Renewal Initiative. More appropriate guidelines and regulations should be drafted to reflect the relative risk of the product.

Research

38. **National Repository:** The ONHP should establish itself as a national repository for current NHP research that will assist in the development of future research proposals.

39. **Peer Review:** The ONHP should act as a disseminator of peer-reviewed published research and other reliable information to researchers, consumers and all other interested parties.

40. **Catalyst for Wellness-centered Research:** The ONHP should foster research on natural health products in the areas of safety, effectiveness, quality and health economics by acting as a catalyst in the stimulation of wellness-centered research, utilizing NHPs.

41. **Research-based Market Incentives:** The ONHP should develop market incentives to encourage continued research into new claims for established products.

Communications

42. **Support and Promotion of the ONHP:** The Minister of Health should offer visible public support and promotion of the ONHP through media activities focussing on the work of the Office as well as NHP policy and/or regulatory changes; the Minister should incorporate Health Canada's commitment to NHPs as part of all public representations on wellness.

43. **Stakeholder Consultation:** The ONHP should move quickly to utilize the communication tools outlined in its Strategic Communications Framework and develop a process for stakeholder consultation on proposed regulatory changes in concert with the new Office of Consumer Affairs and Public Involvement.

Position Statements

44. **Wellness – ONHP as a Catalyst for Change:** The mandate of the new ONHP should be expanded to allow it to function as an effective catalyst for change toward a more holistic

and pro-active, wellness-centered model of healthcare delivery in Canada. As an agent for such change, the ONHP should:

a) increase public awareness of the benefits of prevention, wellness and self-care;
b) promote lifestyle change and the benefits of prevention, wellness and self-care, particularly among our youth and emerging adult sectors;
c) promote a wellness model of healthcare delivery that accommodates and celebrates the cultural and ethnic diversity of Canada;
d) encourage research that further defines the benefits of prevention, wellness and self-care with respect to health optimization and risk reduction; and,
e) act as an International Ambassador for a wellness-centered model of health management.

45. **Wellness – Minister's Role:** The Minister of Health should become the 'Champion of the Cause' for wellness and work toward establishing Canada as a global leader in the evolution toward a more holistic, pro-active and wellness-centered, healthcare paradigm.

46. **Wellness – Financial Incentives:** The Minister of Health should work with stakeholders and other government authorities to develop a comprehensive program of incentives which will promote greater use of prevention, wellness and self-care by Canadians.

47. **Codex Alimentarius:** A position paper should be prepared outlining Canada's new position on NHPs for dissemination to all government officials with responsibility for international trade and relations, including Canada's Codex delegation. This briefing document should delineate the following:

a) the background leading up to the Minister's announcement of the new Office of Natural Health Products and its regulatory regime;
b) the definition and scope of NHPs within the new regime;
c) the new regulatory class of NHPs as separate from foods and drugs;
d) an organizational overview of the new Office of Natural Health Products and identification of relevant contact points;
e) a summary of key initiatives to be undertaken;
f) a strategic approach to facilitate the dissemination of Canada's new position on NHPs to relevant foreign officials; and,
g) a strategic approach to facilitate the dissemination of Canada's position on the regulation of NHPs at the next meeting of Codex, to be convened in Bonn, Germany in June, 2000.

48. **Genetically Modified Organisms – Labelling:** Consumers should be allowed to make an informed choice through mandatory GMO labelling of genetically modified NHPs and excipients. In the interim, the ONHP should create a framework and develop standards to allow the labelling of non-GMO natural health products, including both active ingredients and excipients, and should liaise with other government departments and agencies to effect the necessary changes to make this possible.

49. **Cultural Considerations – Guidelines for Use:** The ONHP should be cognizant of traditional and culturally-based practices and, where circumstances require, give full consideration to, and tailor specific guidelines for, the use of culturally-based NHPs.

50. **Cultural Considerations – Standards of Evidence:** The ONHP should recognize and accommodate the traditional cultural references, terminologies and concepts of ethnic minorities as part of the standards of evidence for purposes of licensing, and ensure proper and thorough consultation by engaging respective cultures and foreign governments as a necessary part of the ONHP's consultation process.

51. **Role of the Practitioner:** a pan-Canadian conference of federal, provincial, territorial and First Nation health representatives, and leaders and educators of the various traditional associations and teaching institutions, and practitioners should be convened to initiate and facilitate communication and education of all stakeholders. The objectives of this process should include:

    a) education and sensitization of federal, provincial and territorial governments on natural healthcare (NHC) practitioners' practices and conventions;
    b) education and sensitization of NHC practitioners to government regulatory and safety issues;
    c) education of governments on current impediments to traditional practices;
    d) implementation of joint efforts to support and better regulate the practice of traditional medicines in Canada within the context of insuring public safety; and,
    e) publication of conference proceedings and position papers to facilitate the development of appropriate regulatory frameworks at the provincial and territorial levels.

It is with a sense of pride and accomplishment that the Transition Team for the *Office of Natural Health Products* presents the foregoing recommendations to the Minister of Health, unanimously endorsed by all members of the Team.

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1.0 Creating the Vision

On March 26, 1999, the Minister of Health, the Honourable Allan Rock, announced the government's acceptance of all 53 recommendations made by the Standing Committee on Health in its 1998 report on natural health products.[1] In accordance with the Standing Committee's report, the Minister acted to initiate the creation of a new Office of Natural Health Products (ONHP) under the direction of the Assistant Deputy Minister, Health Protection Branch. In addition, the Minister announced the creation of an ONHP Transition Team to ensure an appropriate process to build public confidence in a new approach to the regulation of natural health products (NHPs).

> *Natural Health Products: A New Vision*
>
> *3. The government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch.*

Commissioned by the Minister in May, 1999, the ONHP Transition Team was composed of seventeen members, including three government representatives, a consumer advocate and thirteen external representatives with a broad range of experience in the area of natural health products. The Transition Team reported directly to the Assistant Deputy Minister, Health Protection Branch. This report and its recommendations are the culmination of its efforts.

1.1 Terms of Reference

> *Natural Health Products: A New Vision*
>
> *53. The Minister appoint, immediately, a transition team responsible for ensuring the new framework is established quickly.*

The mandate of the ONHP Transition Team was to develop an administrative and regulatory framework and identify broad policy directions to assist Health Canada in implementing the 53 recommendations made by the Standing Committee on Health in its landmark report.

In establishing its *Terms of Reference* the Transition Team agreed

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1 *Natural Health Products: A New Vision.* Report of the Standing Committee on Health, November 1998.

that fourteen members, duly assembled, constituted a quorum for the transaction of business. Recommendations were developed through a process of consensus building and, where unanimity was not achieved, voting members registered their decisions through the Chair. Only Transition Team members were allowed to vote, with motions requiring an 80% (quorum level) approval. Following each meeting the Transition Team distributed for public consumption a summary of its activities and proposed recommendations.

Since its inception, the Transition Team has made substantive progress in conceptualizing and developing an operational framework for the newly created Office. During the process, the Transition Team moved forward on a number of fronts, including:

a) creation of a mission and vision statement for the ONHP;
b) development of screening criteria for the position of Executive Director;
c) development of an efficient, cost-effective, non-hierarchical organizational model and delineation of administrative responsibilities;
d) development of an interim management strategy for the ONHP;
e) formation of the operational structure and qualification criteria for the Expert Advisory Committee (EAC);
f) proposal of an interim Transition Advisory Team (TAT, see Section 2.7);
g) development of a definitional guideline of a natural health product (NHP) and advancement of a regulatory framework, based on a risk-management approach;
h) development of ONHP product and site licensing criteria;
i) creation of guidelines for good manufacturing practices (GMPs), product monographs, determination of risk, labelling, penalties for non-compliance, cost recovery and appeals mechanisms;
j) investigation of necessary changes to current regulations;
k) development of a mandate and key research priorities for the ONHP Research Program;
l) roll-out of a pro-active communications strategy;
m) development of position statements on Codex Alimentarius, genetically modified organisms (GMOs) and cultural considerations; and,
n) presentation of additional recommendations dealing with wellness and a holistic approach to contemporary healthcare.

The task has been provocative, enlightening and rewarding. Throughout the process, the Transition Team has been guided by the touchstone of a recognized need for an effective and efficient approach to regulation – one which will ensure, for all Canadians, full access to a

broad spectrum of high quality natural health products. This report and its recommendations *form a blueprint for action* and set the foundation for a fresh start in the regulation of natural health products in Canada.

1.2 Mission Statement

In the movement toward a more holistic, wellness-centered model of healthcare, Canadians are demanding greater freedom of choice in managing their own health. They are also seeking assurance that the natural health products (NHPs) they purchase are safe, effective and of high quality. Such changes call for the creation of a new regulatory structure, one which acknowledges the right of Canadians to informed choice and respects the philosophical and cultural diversities of approaches to self care.

Natural Health Products: A New Vision

12. The new regulatory authority assume primary responsibility for assessing safety of products.

The Transition Team recommends that:

the mission of the Office of Natural Health Products shall be to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity.

1.3 Vision Statement

To empower this declaration of mission the Transition Team has articulated the following vision for the new ONHP.

The Transition Team recommends that:

the new Office of Natural Health Products shall be:

a) acknowledged as the national authority for the regulation of natural health products used in Canada;
b) recognized worldwide as a leader in natural health product regulation;
c) a leading national and international partner in the management of natural

health products; and,

d) the vehicle for Health Canada to create and maintain an innovative regulatory environment, based on a wellness model that will set a global standard in natural health product regulation.

Canada's ONHP will chart a new course in the regulation of natural health products in Canada and abroad. In all facets of its operations, the new authority will embody a fresh approach, one which ensures ready access to quality NHPs and encourages and promotes a holistic approach toward the optimization and maintenance of health.

2.0 Organizational Structure

Throughout its deliberations the Transition Team recognized the need to design an innovative regulatory system for natural health products in Canada, which encourages the full participation of clients, stakeholders and the public. Critical to this task is the assurance that the organizational structure promotes open and transparent decision making and serves as an incubator for new ideas and novel approaches to product regulation and public awareness of NHPs.

Natural Health Products: A New Vision

3. The Government give consideration to the advisability of creating a new regulatory authority for NHPs that reports directly to the Assistant Deputy Minister of the Health Protection Branch.

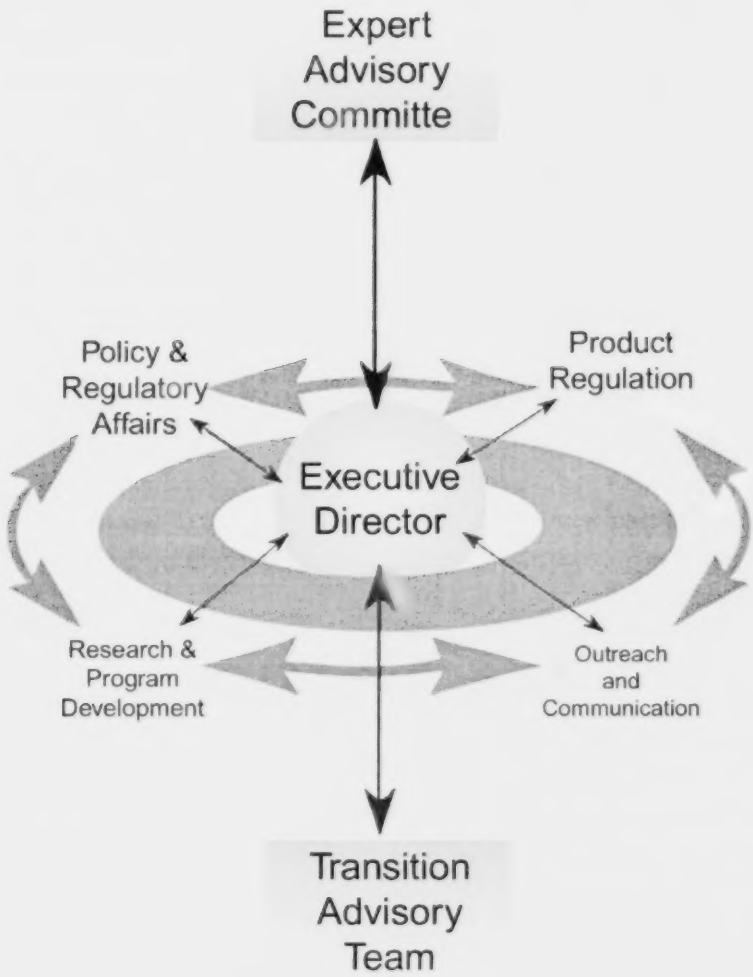
4. The structure for this new regulatory authority be established within the next six months and be permanently staffed by individuals with expertise and experience in the field of NHPs.

5. The selection of personnel be agreeable to both government and NHP stakeholders.

Staffed with individuals with expertise in the field of NHPs, the ONHP is envisioned to be a lean, efficient and flexible organization, which can adjust to varying demands quickly and effectively. Open, creative, accountable and entrepreneurial, the proposed structure of the Office and its administrative positions is non-hierarchical; decision making and delegation of authority are more horizontal than vertical in nature. Such a structure encourages synergy and teamwork rather than confinement to rigidly defined roles of authority (see operational model, page 9).

The Executive Director acts as the central coordinator, while individual directors, or Team Leaders, oversee the areas of product regulation, research and program development, policy and regulatory affairs, and outreach and communications. Division of labour into these management teams or *Points of Delivery (PODs)* encourages innovation, teamwork, synergy, flexibility and cost efficiency. It is proposed that central staffing requirements be minimal, with a small core of staff fulfilling daily office tasks and responsibilities for each POD. It is also proposed that much of the work be out-sourced, thus negating the natural tendency of inefficient and self-perpetuating bureaucratic growth. Such out-sourcing must, necessarily, be accomplished in a manner which maintains the integrity of the ONHP, its mandate and its mission.

Organizational Model of the ONHP



2.1 Executive Director

The Executive Director leads the ONHP and reports to the Assistant Deputy Minister, HPB, Health Canada. The Executive Director will solicit counsel, as desired, from the Expert Advisory Committee (EAC) and from the Transition Advisory Team (TAT) on matters where guidance is sought. The Executive Director orchestrates the strategic direction of the ONHP, providing vision, purpose and principle-centered leadership. Specifically, the Executive Director:

a) develops integrated and coordinated approaches in managing policy and program files on behalf of the Assistant Deputy Minister;
b) consults on an ongoing basis with the EAC;
c) directs the implementation of a policy and regulatory framework for evaluating the evidence supporting claims, safety and quality of NHPs;
d) provides communications activities and coordinates policy activities across Canada;
e) liaises with central agencies on key policy directions;
f) represents Health Canada with major clients and partners;
g) promotes across Health Canada the current government and ministerial priorities;
h) advises senior management on evolving policy, political and societal developments, and their impact on corporate priorities and planning;
i) provides ongoing pulse-taking and analysis;
j) develops and tracks progress in the implementation of the ONHP business plan; and,
k) provides leadership in utilizing the ONHP as an instrument of change and a catalyst in propelling Canada toward a more holistic and wellness-centered, healthcare paradigm.

After considerable deliberation regarding the specifics of this key position, the posting was advertised nationally and a final candidate hired. Phil Waddington, ND, has now assumed his post with the Office.

Natural Health Products: A New Vision

51. Health Canada work with Foreign Affairs and International Trade to ensure that existing International Agreements that currently protect biological diversity are not violated and that additional strategies are developed if needed to prevent depletion of these valuable health resources.

2.2 Director, Policy and Regulatory Affairs

The Director of Policy and Regulatory Affairs is accountable for conceptualizing and designing the required regulatory and policy framework for the ONHP, defining relevant policy issues and developing methodologies for policy analysis and program design.

The Director provides strategic and tactical advice to senior management regarding program, policy and legislative issues and liaises extensively on ONHP priorities, including legal and product definitions, standards, compliance and enforcement. The Director provides direction and support for related policy and program development within and outside Health Canada, works with the EAC and stakeholders to develop and implement an ONHP regulatory, product licensing and administrative framework, and contributes to the strategic direction of the ONHP as a member of the management team.

2.3 Director, Research and Program Development

> *Natural Health Products: A New Vision*
>
> *45. The federal government research bodies, including Health Canada, begin immediately to encourage research on NHPs. This could include studies focussing on the interactions of herbal products with conventional medications as well as studies that explore different uses by various groups in Canada.*

The Director of Research and Program Development is accountable for developing and implementing the ONHP's strategic research agenda, identifying relevant research needs, overseeing the development of a research framework and strategy for the ONHP, evaluating the effectiveness of the research framework and directing adjustments to approaches and methodologies. The Director liaises with and negotiates research partnerships with other federal, provincial, territorial and private agencies in order to attract additional research funds from external sources, integrates and distributes relevant NHP research findings to stakeholders and contributes to the strategic direction of the ONHP as a member of the management team.

2.4 Director, Outreach and Communications

> *Natural Health Products: A New Vision*
>
> *42. Health Canada immediately utilise existing formats and forums for more open and transparent communication on NHPs with the broader public and practitioners.*
>
> *43. Communication efforts include details about decisions and actions regarding NHP products (removal from market, change of status, etc.)*
>
> *44. Relevant consumer, industry and practitioner groups be consulted on a regular basis about the nature of the required information.*

The Director of Outreach and Communications oversees the day-to-day information and communications needs of the ONHP and its interactions with other government agencies, stakeholders and the general public. The Director works with other ONHP Directors to fulfill demand for information from all stakeholders, both domestic and foreign, including: other governmental and non-governmental agencies, practitioners, educators, researchers, suppliers of NHPs and the general public.

The Director is accountable for conceptualizing and implementing a communications strategy to allow Canadians to make informed

choices on NHPs. The Director manages the development of a strategic communications plan for the ONHP, develops a consultative process on proposed regulatory changes, and evaluates and identifies public needs with regard to NHPs. As well, the Director contributes to the strategic direction of the ONHP as a member of the management team.

2.5 Director, Product Regulation

Natural Health Products: A New Vision

48. The new regulatory framework for NHPs be enforced in a regular and consistent manner and done in conjunction with education.

7. All relevant inspection personnel be provided with training specific to NHPs.

18. Inspection activities be performed consistently and on a regular basis by inspectors knowledgeable about the products.

The Director of Product Regulation is accountable for implementing criteria, standards and review processes for facility and product licensing and the evaluation of product safety, quality and claims. The Director oversees the development of product monographs and databases for NHPs, regulates product labelling and marketing, and implements inspection, investigation, enforcement and post- market surveillance. The Director recommends to the Executive Director the issuance of product/facility licenses, manages GMP inspection and NHP compliance procedures, and contributes to the strategic direction of the ONHP as a member of the management team.

The Transition Team recommends that:

the organizational structure of the ONHP, including the Executive Director, Director of Policy and Regulatory Affairs, Director of Research and Development, Director of Outreach and Communications, and Director of Product Regulation, as outlined in Sections 2.1 to 2.5 of the report, be accepted as proposed.

The Transition Team further recommends that:

the ONHP should ensure that field inspectors carrying out the duties of the Office are trained and knowledgeable about NHPs and that inspection duties are performed consistently and on a regular basis to ensure uniform enforcement of regulations across the country.

2.6 Expert Advisory Committee

The Expert Advisory Committee (EAC) has been populated with individuals having strong knowledge and experience with NHPs in order to provide expert advice and opinion to the ONHP. Issues of interest related to the safety, quality and effectiveness of natural health products and matters regarding the development and implementation of regulations for NHPs may be referred to the EAC. The collective expertise from the EAC will assist the management team in making decisions; however, final responsibility and authority remains within the ONHP. The EAC reports directly to the Executive Director, ONHP.

2.6.1 Mandate

The mandate of the EAC is to provide the ONHP with timely, expert advice with respect to questions on the safety, use and regulation of NHPs. Questions referred to the EAC from the ONHP may be from a broad range of issues, but will focus on areas where detailed or difficult evaluation is required. Such issues referred for advice and recommendation may include (but will not be limited to) the following, as required:

a) providing advice to implement the new regulatory environment;
b) developing procedures to create new Canadian monographs based on nationally and internationally collected information;
c) establishing specific requirements for product labelling;
d) evaluating data sources used to establish safety, quality and health claims;
e) evaluating data submissions to establish safety, quality and health claims;
f) providing advice on specific issues related to reported adverse reactions, incidents and effects;
g) evaluating critical situations concerning the safety of a product or ingredient; and,
h) advising on research needed to support regulatory decisions.

2.6.2 Membership

The inaugural EAC has been proposed by a screening committee selected by the Assistant Deputy Minister (ADM), Health Protection Branch (HPB) in consultation with members of the Transition Team. The EAC will be chaired by a member external to the Public Service of Canada and chosen by the ADM, HPB. Subsequent members and Chairpersons will be chosen by the Executive Director, ONHP.

Members have been, and will be, identified through broad consultation with stakeholder groups, including: health professional and scientific societies, academia, industry associations, consumer associations and government agencies. The membership of the committee will endeavour to reflect an appropriate blend of gender, regional, ethnic and linguistic representation for Canada.

Members have been, and will be, selected for their knowledge and expertise in NHPs. Members have been, and will be, appointed as individuals on the basis of their expertise and will not represent their firms, organizations or associations directly. They will serve in the best interests of all Canadians, recognizing the roles and responsibilities of all stakeholders in optimizing access to, and the safe use of, NHPs.

The EAC may form sub-committees or seek out ad hoc members, where necessary, to ensure adequate expertise on matters referred to the committee. Sub-committee and ad hoc members will be selected by the EAC with the concurrence of the Executive Director.

Health Canada staff will provide secretariat support and may actively participate in discussions, as observers, at the call of the Chair.

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9. An Expert Advisory Committee be established immediately to assist Health Canada in the general and specific tasks necessary to design a new NHP regulatory environment.

10. This Expert Advisory Committee review the re-establishment options for an NHP section with research and laboratory capacities and report its findings to Health Canada.

11. The selection of members for the Expert Advisory Committee be agreeable to both NHP stakeholders and Health Canada.

6. When necessary, working groups reflecting the various segments that make up the NHP category be set up to advise the new regulatory authority.

2.6.3 Tenure

The EAC Chairperson and committee members will be appointed for a two or three year term at the discretion of the Executive Director, ONHP. There may be consideration for re-appointment to office up to a maximum period of six years. Appointments shall be scheduled to ensure continuity and systematic rotation of membership within the EAC. Committee members who are absent from three consecutive meetings of the EAC may forfeit membership in the committee.

An individual may withdraw from service on the EAC at any time, upon written notification to the Executive Director. Membership may be terminated at any time, upon written notification from the Executive Director.

2.6.4 Management and Administration

The EAC will be managed and operated under the guidelines for Expert Committees established by Health Canada. These include security and conflict of interest issues as well as administrative guidance regarding compensation and management of the committee activities.

2.6.5 Compensation

Members of the EAC will be remunerated for time and compensated for travel expenses, according to Federal Government policy.

The Transition Team recommends that:

> ***the mandate and structure of the Expert Advisory Committee, as outlined in Section 2.6 of the report, be accepted as proposed.***

2.7 Transition Advisory Team

While not specified in the recommendations of the Standing Committee on Health, the ONHP Transition Team identified the need to ensure that the vision and spirit of the 53 recommendations continue to be reflected in the new operational framework. The Transition Team agreed on the need for an ongoing management advisory body, to consist of a sub-group of Transition Team members. Such a body will ensure a continuity of vision and carry forward the spirit and intent of the Standing Committee recommendations and the

subsequent work of the Transition Team.

The Transition Team recommends that:

a sub-group of four to five ONHP Transition Team members, with a quorum being three members, should be retained on an interim basis to serve as a Transition Advisory Team (TAT). The TAT should be assembled at the call of, and report to, the Executive Director. The TAT should provide ongoing advice and counsel to help ensure that the vision and intent of the Standing Committee and ONHP Transition Team recommendations continue to be reflected in the new Office and operational framework. While travel and accommodation expenses should be paid, members should not receive any remuneration for their counsel.

The Transition Team further recommends that:

Upon the winding down of the TAT, the Executive Director should ensure that a consumer representative, having strong knowledge in and experience with NHPs, be appointed to the EAC.

2.8 Management of NHPs within HPB

The Transition Team recognizes that there may be activities within the Health Protection Branch (HPB) that will overlap and duplicate the activities of the ONHP. The Transition Team also recognizes the ONHP as the pre-eminent regulatory body for natural health products.

The Transition Team recommends that:

The Assistant Deputy Minister, HPB, should:

a) ***play a strong role in coordinating the policy and regulatory activities of the Branch's various regulatory units with respect to NHPs;***

b) ***ensure that such policy and regulatory activities do not result in duplication and/or inconsistent regulation; and,***

c) ***immediately begin to coordinate regulatory activities based on the leadership provided by the ONHP.***

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52. The interim enforcement policy regarding NHPs continue to be applied until the new framework is in place.

The Transition Team further recommends that:

In the interim and until such time as the regulatory framework is fully implemented, Health Protection Branch (HPB) immediately implement an Interim Management Policy for the current regulation of NHPs. This policy should include the following:

a) ***the ONHP Executive Director should be the level of interim management contact and decision making;***

b) ***all matters of regulatory action on NHPs (or those products deemed NHPs under the ONHP's working definition) proposed by any HPB Directorate or other branch of Health Canada, should be undertaken through the ONHP; and,***

c) ***all regulatory decisions and actions should be conducted in an open manner and reported with full explanatory communications to all stakeholders and the Canadian public in a timely fashion.***

3.0 Regulatory Framework

Consumers today are becoming pro-active, demanding greater access to natural health products and accepting greater personal responsibility for their health. The NHP framework is being created in response to increased consumer demand for enhanced self-care options and new approaches to the promotion of wellness. This framework will ensure freedom of choice by balancing access to a variety of products with assurances that these products are safe, effective and of high quality.

Considerable effort has gone into the development of an appropriate regulatory framework for NHPs, which encompasses the spirit of the recommendations of the Standing Committee on Health and the original Advisory Panel on Natural Health Products. The Transition Team envisions a framework which incorporates a relative risk-management approach to the regulation of NHPs. This framework includes necessary evidence-based requirements, which transcend exclusive reliance on clinical research and reflect the divergent cultural approaches to wellness. To ensure consumer confidence in NHPs the system will remain flexible and innovative, capable of adapting to new products as well as new approaches to healthcare.

3.1 What is a Natural Health Product?

The architecture of the regulatory framework is dependent on the definition of a natural health product. Such a definition will direct the proper allocation of resources to administer the regulations and establish a clear delineation of NHPs between foods, on the one hand, and pharmaceuticals on the other. This approach implies the need to coordinate policy between the agencies responsible for foods (Food Directorate), natural health products (Office of Natural Health Products) and pharmaceuticals (Therapeutic Products Programme).

The Transition Team has created the following guidance principles to serve as a definitional template for a further legal interpretation of NHPs.

a) Natural health products (NHPs) are composed of substances or combinations of substances found in nature, and energetically-potentized preparations, used for the purpose of maintaining or improving health or treating or preventing

diseases/conditions.

b) NHPs include, but are not limited to, the following: homeopathic preparations; vitamins; minerals; enzymes; co-enzymes; co-factors; herbs or botanicals; naturally-occurring animal, plant and micro-organism substances; and, a variety of molecules extracted from natural sources, such as amino acids, polysaccharides, peptides, naturally occurring hormones and biochemical intermediates, as well as naturally occurring molecules synthesized by chemical or biological means.

c) Loose herbs which have health claims, or for which there are known contraindications, should be classified as NHPs. The ONHP and Food Directorate should coordinate their policy efforts in order to ensure that herbs with known contraindications are regulated under the NHP framework.

d) It is recognized that NHPs are generally used and best managed within the context of a wellness, holistic medical paradigm that optimizes health. The use of NHPs forms part of the lifestyle, belief systems, cultural habits and traditions of individuals. Consequently, the regulatory framework should augment the individual's freedom of choice in accessing NHPs.

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1. Health Canada, in conjunction with a new separate NHP Expert Advisory Committee, set out an appropriate definition of NHPs and amend the Food and Drugs Act accordingly.

2. Health Canada, in conjunction with the new NHP Expert Advisory Committee, examine the status of bulk herbs for legislative purposes.

The Transition Team recommends that:

the ONHP and Health Canada should work toward appropriate legislative or regulatory change to ensure that the legal interpretation of natural health products (NHPs) clearly differentiates these products from foods and pharmaceuticals.

3.2 Licensing

Throughout its deliberations the Transition Team has recognized the inherent safety of NHPs. It is the consensus of the Transition Team that products of lower risk require lower regulatory barriers to the market. On the other hand, any NHPs which pose significant risk should require more stringent regulatory control.

Regulatory stringency should reflect the level of risk, whether inherent in the produc the

growing, harvesting or manufacturing process, or through product claims. In its approach, the Transition Team has sought to strike a balance between the consumer's desire for freedom of choice and the ONHP's mandate to ensure safety, quality and effectiveness.

3.2.1 Site Licensing

The establishment of site licensing is necessary to enable the ONHP to ensure that good manufacturing practices (GMPs) are employed in the production of NHPs sold in, or into, Canada. Licensing of primary facilities will also enable the ONHP to expeditiously enable a product recall, if necessary.

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12. The new regulatory authority assume primary responsibility for assessing safety of products.

17. Manufacturers, packagers, importers and distributors of NHPs, whether located in Canada or abroad, be obliged to hold valid establishment licenses.

37. When the new regulatory framework is implemented, the personal importation policy be reviewed by Health Canada and the Expert Advisory Committee to determine if it is still appropriate and to outline permissible changes.

The new regulatory authority will have primary responsibility for assessing the safety, quality and claims of NHPs. In developing the following recommendations the Transition Team reviewed all potential sites along the processing chain, from grower to consumer, that may be subjected to licensing by the ONHP.

The Transition Team has set forth the following criteria deemed essential for an effective site licensing program:

a) products not originating from an ONHP-licensed facility shall not be sold in, or into, Canada;
b) for NHPs manufactured and packaged in Canada, the facility undertaking the manufacture (encapsulation, tableting and bottling), packaging or repackaging of these products should be licensed;
c) the facility of an importer/distributor that is the first point of commerce within Canada for products manufactured or packaged outside of Canada should be licensed;
d) multi-level marketing (MLM) companies that have a presence (warehouse/distribution centre, etc.) in Canada should be the holder of said license;
e) facilities not physically located within Canada shall be licensed, subject to appropriate guidelines developed by the ONHP;
f) the holder of a license, as a term of the license, should be responsible for ensuring that all facilities and handlers of NHPs or NHP raw materials within their supply chain are in compliance with appropriate GMPs, as set out by the ONHP;
g) site inspections and audits should be carried out in the most efficient and cost-

effective manner and, if necessary, out-sourced to approved third parties;

h) service fees should not be flat-rated, but adjusted for the size and activity of the facility;

i) as provisions to reduce costs for small businesses are desirable, consideration should be given to spreading out initial inspection and audit costs over a two or three year time frame to lessen the financial impact on the smaller facility;

j) once a site or facility has a license, spot-audits should be carried out periodically, as determined by the ONHP;

k) while there would be no cost for spot-audits, any resulting re-inspection costs should be born by the facility; and,

l) all analytical laboratories contracted to verify the safety, quality and claims of NHPs should be licensed.

The Transition Team recommends that:

the specified criteria deemed essential for an effective ONHP site licensing program, as outlined in Section 3.2.1 of the report, be adopted as proposed.

The Transition Team recognizes that there may be reasonable grounds for individuals to obtain, for their personal use, limited quantities of products from outside Canada.

The Transition Team further recommends that:

the ONHP, in conjunction with Health Canada's Legislative Renewal Initiative, develop a regulatory provision which clarifies the reasonable grounds respecting the importation of NHPs for personal use.

3.2.2 Product Licensing

In its report, the Standing Committee on Health recommended the creation of a product licensing system based on available monographs and reliance on pre-market approval. Its report also recommended that manufacturers of products which do not have monographs should be required to provide sufficient evidence to Health Canada before products are marketed. The level of evidence required should be consistent with the margin of risk associated with the product.

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31. The new framework be phased in over a period of months to allow sufficient time for the stakeholders and the regulator to review the current DIN system and conform to the new regulations.

The intent of product licensing is to assess and manage risk. The Transition Team envisions a product licensing system that will protect the health of the public and that is efficient, fiscally responsible and effective in ensuring accessibility and safety of NHPs. The product licensing system proposed by the Transition Team would meet this mandate while minimizing regulatory burden and would rely on a quality assurance approach through the use of site licenses, GMP standards for safety and quality, and standards of evidence for claims.

3.2.2(a) Guiding Principles: The Transition Team has set out the following guiding principles to facilitate the development of an effective product licensing system.

a) there should be no more regulation than necessary, but no less;
b) because the quality and safety of NHPs are best addressed by an effective site and product licensing program, a valid site license should be a prerequisite for the issuance of a product license;
c) penalties for non-compliance which provide deterrents should be an important and integral part of the product licensing system;
d) the level of product assessment should be appropriate to the level of uncertainty associated with the product;
e) a means of establishing a product registration number for product licenses should be developed, which ensures that duplicate registration numbers are not assigned; and,
f) for products currently on the market, there must necessarily be a phase-in period to allow manufacturers, distributors and importers sufficient time to come into full compliance with product and site licensing requirements.

The Transition Team recommends that:

the Guiding Principles for developing a product licensing system, as outlined in Section 3.2.2(a) of this report, be adopted as proposed.

3.2.2(b) Monographs: The Transition Team recognizes that there are two basic methods for establishing the safety, quality and claim of products, namely:

a) the use of available evidence, including non-attestable monographs, on a product-by-product review and assessment process; and,

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26. A product licensing system based on monographs be used when they are available. Such a system should rely on a pre-market approval process and the regulator should have a short period of time (for example, 30 days) to review the application.

b) the use of ONHP-approved attestable monographs, against which lower risk product applications can be audited.

In the case of lower risk products, the proposed product licensing system will rely, in part, on ONHP-approved, attestable monographs, which will form the basis for an abbreviated pre-market process. Such monographs will be established by the ONHP through consultation with stakeholders and the EAC and will contain appropriate information on items such as quality, safety, claims and references. Substances proposed for these monographs will be evaluated against the risk factors to establish that they are of lower risk. The ONHP may also adopt, by reference, existing monographs which meet the requirements for an attestable monograph. A list of these ONHP-approved attestable monographs will be prepared and made available to all stakeholders.

Non-attestable monographs for higher risk products, or for lower-risk products which do not lend themselves to the attestable monograph process, can also be created as knowledge is acquired. These non-attestable monographs will serve stakeholders and the ONHP for the assessment process and for post-market monitoring processes required to manage higher risk products. Through appropriate regular review, the ONHP will ensure that monographs are kept up to date, especially in regard to the assessment of risk.

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20. Claims be assessed to ensure that there is reasonable evidence supporting the claim.

21. The evidence not be limited to double blind clinical trials but also include other types of evidence such as generally accepted and traditional references, professional consensus, other types of clinical trials and other clinical or scientific evidence.

22. The evidence required vary depending on the type of claim being made, with different evidence being required for structure-function claims and risk-reduction claims for minor self-limiting conditions than for therapeutic or treatment claims.

The Transition Team recommends that:

the ONHP adopt a process for product licensing which relies on two basic methods for establishing the safety, quality and claim of products:

a) the use of available evidence, including non-attestable monographs, on a product-by-product review and assessment process; and,
b) the use of ONHP-approved attestable monographs against which lower risk product applications can be audited.

The Transition Team further recommends that:

Monographs should be subject to a process of regular review, update, revision and assessment of risk.

3.2.3 Proposed Product Licensing System

The product licensing system proposed by the Transition Team is designed to allow the ONHP to focus the major part of its resources on new products and new claims. While respectful of the Standing Committee's recommendations for a pre-market approval process for all products, the Transition Team examined both pre- and post-market notification options to determine the optimal system in meeting its product licensing objectives for efficiency, fiscal responsibility, product accessibility, quality, claims and safety. The system is outlined as follows.

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24. The new product licensing framework be based on a risk management approach that emphasizes the margin of safety associated with a particular product.

25. Health Canada, in conjunction with the Expert Advisory Committee, establish categories within the NHP class to determine what level of regulation is appropriate for a particular product.

27. Health Canada, in conjunction with the Expert Advisory Committee, establish procedures to create new Canadian monographs based on work already accomplished in other countries.

28. Manufacturers of products that do not have monographs be required to provide evidence to Health Canada before a product is marketed. The level of evidence would be consistent with the margin of safety associated with the product.

3.2.3(a) Lower Risk Products with Attestable Monographs: Where there is a product deemed of lower risk which meets an ONHP-approved attestable monograph, an abbreviated assessment (audit) will be conducted within 45 calendar days as a performance standard. Prior to introducing the product into the Canadian marketplace, a site license holder must submit an application accompanied by an attestation that the product meets the monograph.

Upon receipt of the application, the ONHP will assign a provisional registration number to the product and provide it to the applicant with an acknowledgment of receipt. The applicant would be authorized to use the registration number and introduce the product into the marketplace upon written notice without objection from the ONHP or after 45 calendar days have elapsed if no notice of objection is delivered to the applicant within that time.

The Transition Team recognizes that the ONHP-approved, attestable monograph approach to product licensing can provide Canadians with timely access to safe products which are of high quality and carry valid claims, and that product usage should be optimized. However, it is acknowledged that there will be a time lag between the startup of the NHP regulatory framework and the assessment and development of attestable monographs.

The Transition Team recommends that:

the ONHP adopt an approach to optimizing the use of ONHP-approved attestable monographs which has, as its initial approach, a pre-market audit process with a 45 calendar day limit on government response to the application.

The Transition Team further recommends that:

within 3 years of the coming into force of the new regulations, the ONHP move to further optimize the monograph system. Specifically, a trial project utilizing a post-marketing notification approach to product registration should be implemented and evaluated for a limited number of ONHP-approved attestable monographs. If successful, the ONHP could further expand the use of such a post-market system.

***3.2.3(b) Lower Risk Products without Attestable Monographs*:** Provision of acceptable evidence, consistent with the margin of safety of the product, will be required for assessment of products which do not have ONHP-approved, attestable monographs. The submission will include all necessary information to satisfy requirements for safety, quality and claims (see Standards of Evidence, Section 3.2.5) If approved, a product license and registration number will be assigned, allowing the license holder to release the product into the Canadian marketplace.

The Transition Team recommends that:

for lower risk products without ONHP-approved, attestable monographs, the provision of acceptable evidence, consistent with the margin of safety of the product, should be required for assessment of the product by ONHP.

3.2.3(c) Higher Risk Products: Higher risk products will be subject to initial assessment and continued monitoring.

The Transition Team recommends that:

for higher risk products, performance standards for the review and assessment of submissions should be set, in consultation with stakeholders.

3.2.3(d) Cancellation of Product License: At times, it may be necessary to cancel a

product license. In such circumstances, mechanisms need to be in place to safeguard against the unwarranted removal of safe products from the market. A registration license should not be revoked without significant grounds for such action.

The Transition Team believes that the cancellation of a product licence is the most severe regulatory action available to the Director and all reasonable efforts at compliance should be undertaken prior to cancellation of a licence.

The Transition Team recommends that:

the conditions under which the Executive Director may cancel licenses need to be set out in regulations. Product recall, product seizure and other compliance activities should be available to the Director and subject to a timely appeal process by the marketer.

3.2.3(e) Public Registry: Along with penalties for non-compliance, the Transition Team believes that compliance will be enhanced by making public a list of ONHP-licensed products. Access to such a public registry would provide consumers, healthcare providers, industry and others with a tool to help ensure that products consumed, referred or sold are in compliance with ONHP regulations.

The Transition Team recommends that:

a public registry of all ONHP registered products that is easily accessible by the public and stakeholders should be established; the registry should include the product name, active ingredients, registration number and company name for each product.

3.2.3(f) Electronic Submissions: The application of electronic systems and programs will greatly enhance the ONHP's ability to meet performance standards and expedite the product licensing system in an efficient and cost-effective manner.

The Transition Team recommends that:

an electronic submission system should be established for all product reviews and, in the case of products for which there is an ONHP-approved attestable monograph, an electronic submission and review system for abbreviated assessments (or audits) should be developed.

3.2.4 Good Manufacturing Practices

The Transition Team recognizes that the issues of quality and safety are linked in many ways. One means to ensure that the safety profile represented in product licensing is maintained through the life-cycle of the product is the use of mandatory good manufacturing practices (GMPs). While the nature of each product presents differences in required approaches to specific quality issues, there are some universal areas where GMP regulation needs to set out the minimum legal terms to ensure that the products are safe and of good quality.

The Transition Team believes that the new regulatory framework should provide regulatory outcomes within the following areas:

a) premises should be clean and sanitary, and should be designed so as to prevent the contamination of products;
b) equipment should be maintained and operated in a manner that is clean and sanitary, and should be designed so as to prevent the contamination of products;
c) personnel should have appropriate education, training and experience in order to perform their assigned functions in a safe and effective manner;
d) sanitation procedures should be in place to ensure that manufactured products remain safe and free of contamination;
e) raw material, finished product and packaging testing should be done against written specifications;
f) manufacturing controls should be documented and detailed records kept;
g) quality control personnel should be responsible for quality functions and decisions related to the manufacturing, testing and post-market surveillance of products;
h) records should be kept of critical processes and programs; and,
i) product expiration and shelf-life dates should be supported by data that confirm adherence to label claim at the end of the designated time frame.

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15. Health Canada, in collaboration with the NHP industry, establish appropriate GMP guidelines reflective of the different nature of NHPs.

16. GMP standards for NHPs include specific quality control and testing for herbal products.

The Transition Team recommends that:

the ONHP begin consultation with manufacturers, packagers and importers to develop the specific regulatory requirements and guidelines for good manufacturing practices (GMPs) of natural health products, which will assist inspection and compliance to GMP regulations.

3.2.5 Standards of Evidence

The Transition Team accepts, in principle, the proposals tabled by the Advisory Panel on Natural Health Products regarding the standards of evidence for safety and claims. Under the proposed regulatory framework all NHPs sold in, or into, Canada would be obliged to meet certain minimum standards for safety, quality and claims.

3.2.5(a) General Requirements: The standards of evidence and level of data submission required before the issuance of an ONHP product licence should be linked to the prior general knowledge or marketing experience relating to the safety, quality and the associated claim of the product. The level of evidence required should be a function of the quality of the individual studies, as well as the quantity, quality, consistency and strength of the overall data available and their relevance to the claim. Furthermore, the standards of evidence for health claims on NHPs should be sufficiently rigorous to protect public health interest and enhance consumer confidence. The standards should be flexible to allow industry to develop useful products at a reasonable cost and to accommodate changing scientific developments.

3.2.5(b) Claim: The Transition Team concurs with the recommendations made by the House Standing Committee and the Advisory Panel with regard to types of claim, namely: structure/function, risk reduction and treatment.

All health claims, stated or implied, in advertising, labelling or promotion must be capable of substantiation and must not be misleading. While clinical trials can provide strong evidence, other types of evidence can also be acceptable for NHPs with a safe history of use. It is important to note that the requirements for proof of effectiveness and the documentation required to support the indicated claim should depend on the nature and the level of the indication(s).

Botanicals and certain other NHPs have been shown to vary in content or delivery of active or potentially active components due to factors such as the soil in which the plant

is grown or the method of extraction. Critical factors also apply to the processes of producing an extract and manufacturing a final product in dosage form. Which part, or parts, of the plant are used or discarded, which solvent is used for extraction purposes and for what duration, and at what temperature is the extraction made, demonstrate just a fraction of the critical factors which can influence the quality of the final product and its potential effectiveness with respect to the intended claim.

Pharmaceuticals in dosage form also provide valuable experience in determining effectiveness. Even when the same route of administration is selected, the effectiveness of a product may differ dramatically (or even vanish), depending on whether it is a coated or uncoated tablet, a liquid or a solid, and so on. For phyto-pharmaceuticals (botanicals that have been studied pharmaceutically) this is just as evident. It is known that certain botanicals perform very differently when delivered from aqueous, alcoholic, or oily vehicles; some are even rendered practically inert by the choice.

Current data and experience do not support the inference that evidence derived from the scientific study of one particular botanical form can be used confidently to assess the validity of the same claim in another form of the same botanical or extract. Accordingly, the evidence-based claims of one extract are not rationally transferrable to another extract of the same botanical without distinct evidence of effectiveness.

Considering the foregoing, a manufacturer of an NHP, or its nominee, that has demonstrated a significant clinical effect may be granted a claim. This claim may be approved by the ONHP for any other NHP with acceptable evidence assessed at, at least, the same standard as the original claim.

The Transition Team recognizes that there may be an opportunity to create an ONHP-approved, attestable monograph, or amend existing ones, for the clinically-proven claim of a lower-risk product. However, attestable monographs must carry reasonable references to supporting evidence; such monographs would be provided when such reasonable references are publicly available.

***3.2.5(c) Monographs*:** The EAC, at the request of ONHP, should identify the attestable monograph format for each of the various types of NHPs. Minimum requirements would include identification of the substance(s), claims, quality standards, dose, toxicity, contraindications, warnings or cautions, and references to support each of these. Monographs may contain additional information categories as deemed necessary to provide more information for safety and claims. ONHP-approved, attestable monographs

should be developed in Canada, but may be adopted from non-Canadian sources.

The Transition Team recommends that:

a) ***the evidence to support the safety and claim of a product must not be limited to double blind clinical trials, but may also include other types of evidence, such as generally accepted and traditional references, published monographs, expert opinion reports, other types of clinical trials and other clinical or scientific evidence;***

b) ***the ONHP, with the assistance of the EAC, should establish a list of acceptable references, develop the criteria for ONHP-approved monographs and develop criteria for linking levels of evidence to health claim validity; and,***

c) ***claim approval by the ONHP, on the basis of scientific evidence, should be allowed to be applied to other products with supportive scientific evidence of at least an equal level of claim assessment.***

3.2.5(d) Administrative Lists: The development of administrative lists of NHP categories would facilitate the regulation of NHPs. Rather than remain entrenched in regulatory schedules, the NHP categories should form part of the policy framework for regulation, where they can be more easily amended. Monographs for products within each category should be researched and developed to facilitate the licensing process.

The Transition Team recommends that:

the ONHP develop an administrative list of NHP categories based upon the proposed working definition. The list should include broad categories of products, such as those set out in the working definition, and there should be flexibility in the inclusion of products in the list and a means to amend such a list. Monographs for products which fall into these categories and which meet the criteria developed for monographs used in audit application should be adopted by reference to other standards.

3.2.5(e) Determination of Risk: The Standing Committee on Health recommended that categories be established to determine what level of regulation is appropriate for a particular product. Needless to say, the level of regulation should reflect the level of risk.

The safety of a product is, generally, assessed outside the context of proposed use; but, relative risk is evaluated by examining the safety *within* the context of claim and usage. Lower risk products would be those safely consumed without the intervention of a professional, provided that the consumer is adequately informed through product labelling or other means. Lower risk NHPs would have less stringent licensing requirements than would higher risk products.

In the model proposed by the Transition Team, the concepts of higher and lower risk are set out as key components of product licensing. It is recognized that these are relative terms, rather than an absolute description of risk.

The role of the ONHP is to review products against a risk-assessment standard. Such a standard would set out the factors against which the products would be evaluated. The basic principle of evaluating risk for NHPs should be that, unless a product meets a set of factors which would classify it as higher risk, then it will be classified as lower risk. Thus, the standard against which risk is measured would be the set of factors themselves.

The factors must describe a definitive continuum of risk, along which products will fall. Therefore, there will be a number of considerations which evaluators will need to exercise in order to assess relative risk. These considerations include whether:

a) individualized instructions and/or practitioner supervision or monitoring is required to ensure safety or effectiveness;
b) there is a narrow margin of safety between therapeutic dose and toxic dose;
c) there is significant potential for undesirable or severe side effects at normal therapeutic dosage levels;
d) known experimental data has shown that the product induces toxicity in animals, but the product has not been in clinical use long enough to establish the pattern of long term toxic effects in humans;
e) safe use is known to possibly mask other serious ailment(s) or their development;
f) statistically significant potential for addiction, abuse, severe dependency or other harmful effects has been demonstrated;
g) they possess a low level of safety relative to expected benefits; and,
h) whether they have a therapeutic effect based on recently established

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13. General safety protocols be developed by the Expert Advisory Committee based on EAC judgements of reasonable evidence.

14. When necessary, this regulatory authority establish appropriate working groups to assess the safety of specific products.

pharmacological concepts, the consequence of which has not yet been fully established.

The proposed set of factors would provide consistency with relative risk assessment throughout Canada, as well as with Canada's major trading partners. This would serve to optimize harmonization domestically and internationally, in order to maximize access to quality NHP products for Canadians.

The Transition Team recommends that:

the specified factors deemed essential for an effective determination of risk, as outlined in Section 3.2.5 (e) of this report, be adopted as proposed.

3.2.5(f) Post-Market Monitoring: A system of effective post-market monitoring should reflect the relative risk of the product. Since there is an assumption of safety for NHPs (unless higher risk factors are met) the majority of products should require minimal intervention in post-market surveillance.

In conjunction with relative risk, post-market monitoring should be set up as a condition attached to product licenses with two levels of reporting required:

a) *Lower Risk Products:* would require reporting of new, unexpected or severe adverse events as they occur.
b) *Higher Risk Products:* would require regular reporting of all side effects and all adverse events as they occur.

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29. The level of post-market monitoring be based on the margin of safety associated with the product and include an NHP adverse event reporting system for industry and an adverse reaction hotline for practitioners and the general public.

In accordance with the Standing Committee recommendations, post-market monitoring should include an NHP *Adverse Event Reporting System* (AERS) for industry and an *Adverse Reaction Hotline* (ARH) for practitioners and the public. Furthermore, data collected from post-market monitoring should be assessed on a regular basis by the ONHP for labelling adjustments and other actions, as deemed appropriate. Where NHP interactions are established, this data should be shared with all interested stakeholders.

The Transition Team recommends that:

the specified criteria deemed essential for an effective post-market monitoring program, as outlined in Section 3.2.5(f) of the report, be adopted as proposed.

3.2.6 Product Labelling

The Transition Team wishes to ensure that consumers are provided with information which meets the regulatory requirements for safe use as well as truthful claims. To this end, the Transition Team is in full concurrence with the recommendations of the Advisory Panel on Natural Health Products and has set forth the following criteria deemed essential for the labelling of NHPs.

The regulations for labelling of NHPs should require the following elements on the package label as minimum acceptable consumer information:

a) brand name;
b) ingredients, including a quantitative listing of active ingredients and a qualitative listing of excipients (how these ingredients are specified will depend upon whether the ingredients are herbal, animal, homeopathic, vitamins/minerals, etc.);
c) expiry date;
d) name and address of the site and/or product license holder;
e) lot number;
f) net amount of the product in the container (eg. mL, number of units etc);
g) adequate directions for use (including: dosage, side-effects and cautions or contraindications, where applicable);
h) special storage needs, if applicable; and,
i) unique product identification code, as granted by the ONHP.

Where there is insufficient space on the label to provide this information, a package insert may be used. However, the same small package exemptions that currently exist for these products should remain in force.

Each of these components should be linked to the minimum criteria required to fulfil the regulatory obligations for safe use and factual claims, as well as those elements necessary for compliance and enforcement.

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32. Health Canada consult with its new separate NHP Expert Advisory Committee to determine what information is to be included on the labelling, consisting of, at a minimum, the items recommended by the Advisory Panel on Natural Health Products.

33. NHP labelling provide consumers with all relevant information needed to make informed choices.

34. NHP labelling be standardized to provide clear and consistent product information.

23. The label indicates clearly the type of evidence used to support the claim.

30. Certain lower safety products be made available to consumers with appropriate warnings and other lower safety products only be made available with practitioner intervention.

The Transition Team recommends that:

the specified criteria deemed essential for an effective labelling program, as outlined in Section 3.2.6 of the report, be adopted as proposed.

The Transition Team further recommends that:

the ONHP develop the policy framework to address the spirit and intent of recommendations 23 and 24 of the Standing Committee's report.

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23. The label indicates clearly the type of evidence used to support the claim.

24. The new product licensing framework be based on a risk management approach that emphasizes the margin of safety associated with a particular product.

3.2.7 Penalties for Non-Compliance

The creation of new regulations will enable Canadians to enjoy greater freedom of access to safe, quality products. Under the present system, however, compliance to current regulations is very low. This is partially the result of common knowledge that regulatory enforcement has been, at best, sporadic and weak. In addition, if one is found to be in non-compliance, the probability of prosecution is low. If a charge is laid, the penalty is minimal and is considered by many to be merely the cost of doing business. Fines in the $100 - $150 range are easily recovered in the sale of a case or two of the offending product. Seldom is the fine over $300.

Deterrents against non-compliance need to be established by setting appropriate penalties in the regulations. In addition, the application of enforcement activities needs to be consistent in order to provide a level playing field for all players.

While the new regulatory environment should be seen to be reasonable, realistic and workable, there must be consequences for non-compliance. Rather than create a heavy-handed and punitive bureaucracy, regulations should be developed that stakeholders will accept because they are inherently fair and reasonable.

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48. The new regulatory framework for NHPs be enforced in a regular and consistent manner and done in conjunction with education.

49. Sufficient resources be provided for enforcement activities.

While violations should invoke consequences, the penalties applied should reflect the nature of the violation. Penalties should be targeted to those who attempt to circumvent regulations and the penalty for knowingly making a false attestation should be sufficient to discourage such actions. This is necessary to engender consumer confidence and enhance the credibility of product

labelling.

The ONHP Transition Team recognizes that appropriate penalties for non-compliance should, therefore, be written into the new regulations for NHPs. It also recognizes that revisions will be necessary, from time to time, and that these revisions must be made in a timely manner through appropriate administrative action.

The Transition Team has set forth the following criteria deemed essential, yet reasonable, for an effective program of compliance:

a) appropriate penalties be established to encourage compliance with the NHP regulations;
b) for knowingly making a false attestation, a fine should be established for a first offense, with a higher fine and one year suspension of site license for the second and subsequent offenses (examples of such penalties would be $5,000 for a first offense and $10,000 for subsequent offenses);
c) for knowingly making a false label declaration, a fine should be established for a first offense, with a higher fine and one year suspension of site license for the second and subsequent offenses (examples of penalties would be the same as those outlined above);
d) the penalty for non-compliance should be sufficient to remove the economic motivations for selling non-complying products;
e) for knowingly selling a non-complying product, the penalty should be a series of escalating fines for a first, second, third and any subsequent offenses (examples of escalating fines would be $2,000, $5,000 and $10,000 respectively);
f) for operating without a valid site license, a fine should be established for a first offense, with a higher fine imposed for second and subsequent offenses (examples of fines would be $10,000 and $25,000 respectively);
g) a business owned and/or operated by a principal or principals previously convicted under any of the above sections would be considered to be a repeat offender, even if the business was operating under a different name or corporate entity; and,
h) under the new regulatory framework, all complying NHPs should be licensed by the ONHP.

The Transition Team recommends that:

the specified criteria deemed essential for an effective, yet reasonable, program of compliance, as outlined in Section 3.2.7 of the report, be adopted as proposed.

3.2.8 Cost Recovery

The Standing Committee recommended that Health Canada conduct an analysis of the impact of the overall cost recovery policy on the different segments of the NHP industry and that NHP industry stakeholders be consulted in the establishment of the most appropriate fee structure and amount. In principal, the Transition Team supports the implementation of user charges for services that provide identifiable recipients with direct benefits beyond those received by the general public.

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38. Health Canada conduct a review analysing the impact of the overall cost recovery policy on the different segments of the NHP industry.

39. The NHP industry stakeholders be consulted in the establishment of the most appropriate fee structure and amount.

40. As a result of this review, the existing fee levels be re-examined if necessary.

Section 19 of the Financial Administration Act sets out the authority for the Governor in Council, on recommendation from Treasury Board, to prescribe fees or charges to be paid for a service. It clarifies that such charges "may not exceed the cost to Her Majesty in right of Canada of providing the service." [2] While federal departments have been guided by the cost recovery policy, the principles of the policy are open to broad interpretation, with resultant inconsistencies in application. Consequently, there has been significant growth in regulatory fees in recent years, geared to generating established revenue targets. "Such fees have a pervasive and complex effect on industry and are detrimental to consumers and the competitive position of Canada's businesses." [3]

The Transition Team recommends that:

fees imposed by the ONHP should adhere to cost recovery and charging policy guidelines adopted April, 1997, by federal Treasury Board. In establishing such fees, the ONHP should undertake meaningful consultations with clients to ensure that those who must pay for the service have a voice in the design and delivery of such service. The aim of consultations should be to avoid the imposition of unfair

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2 *User Fees: Where does the Buck Stop?* The Blair Consulting Group, January 1999.

3 Ibid

or unreasonable cost burdens on clients, while ensuring necessary rigour in the licensing and regulatory process. Any fees imposed should be directly related to, and fairly reflect, the cost of service and should be subject to proper impact assessments.

3.3 ONHP Appeals Mechanism

The best efforts of both stakeholders and government in anticipating most issues may fall short in the real world, and there will be opportunities for submission sponsors to move into uncharted territory. When this happens, undoubtedly, there will be disputes over everything from interpretations of guidelines to interpretation of data submitted to support product registration. There is a need to anticipate that there will be such divergences of opinion and that, when this happens, there should be a means to resolve the dispute.

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41 As part of the immediate process for NHPs, Health Canada work with stakeholders to establish appropriate, accessible and effective appeal processes for relevant policies and possible inclusion into a revised regulatory and legislative framework.

In anticipating these challenges, the Transition Team has developed an ONHP Appeals Mechanism based on the principle that, within 30 days of receiving the Director's final decision, a licensee may make a written request that an appeal of the decision be considered by an Appeals Committee. The committee would be constituted as follows.

3.3.1 Committee Structure

The Appeals Committee members should be at arm's length to the decision being appealed in that the appellant may not nominate an employee or any person involved in the situation being appealed, and the Executive Director's nominee should not be under his staff reporting structure. Under these conditions, the following would apply:

a) the Executive Director of ONHP would choose one committee member;
b) the appellant would choose one committee member;
c) the Executive Director and appellant would agree upon either one or three additional committee members, depending on whether the appellant wishes to have either a three or five member Appeals Committee;
d) the Appeals Committee would choose their own Chairperson or, in the case where a Chairperson cannot be agreed upon by the committee, one would be

appointed according to the procedures outlined in the guidance documents for the committee.

3.3.2 Cost of Appeal

While costs for the appeal will have to be subject to further consultation, any cost structure put in place should not form a barrier to appeal for small and medium sized enterprises and should be equitable to all appellants.

3.3.3 Expert Advisors

A pool of experts should be maintained to draw upon for expertise relevant to the issue at hand. Recognizing that some appeals may stem from marketing issues unrelated to specific claim or safety matters, there should be other independent expertise to draw upon for such issues. The EAC should be relied upon for appeals of a technical nature.

3.3.4 Time Frame for Review

An Appeals Committee should conclude its review of a decision within 60 days from the date of the receipt of the letter requesting the appeal. The time for this process should be allocated as follows:

a) 15-20 days for agreement between ONHP and the appellant on the makeup of the Appeals Committee;
b) 15-20 days to conduct the hearing;
c) 15-20 days for the Appeals Committee to deliver its opinion.

3.3.5 Guidance Document

A guidance document should be developed by the ONHP detailing the procedures to be followed for an appeal. This document, among other administrative procedures, should set out how correspondence between parties must be handled in order to achieve the performance targets for an efficient appeal. The document should also set out any variations in process required relative to a decision of refusal to issue a licence versus suspending or cancelling a licence.

3.3.6 Consistency of Application

Where an appeal originates in an HPB office other than the ONHP (eg: Food Directorate), there should be sufficient coordination of the appeal so that similar mechanisms exist in all HPB operational units. The same pool of experts should be used throughout to ensure consistency.

The Transition Team recommends that:

The Appeals Mechanism, including the structure of the Appeals Committee, proposals for cost recovery, use of expert advisors, time frame for review, formulation of a guidance document and proposals for consistency of application,

as outlined in Section 3.3 of the report, be adopted as proposed.

4.0 Modifications to Current Regulations

Throughout it deliberations the Transition Team recognized that there are a number of legislative and regulatory changes which must be effected in order to fully implement the mandate of the ONHP. Discussion centered on whether initial changes should be legislative or regulatory in nature. The consensus emerged that, wherever possible, initial changes should be made to schedules and regulations. It was felt that the timeline for legislative change is prohibitively long and that such change would best evolve through the process of HPB legislative renewal. The Transition Team, therefore, investigated a number of avenues for regulatory change which need to be accommodated in order to clear the path toward operationalizing the ONHP as quickly as possible.

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>
> *8. The necessary process to amend the Food and Drugs Act not delay in any way the implementation of the regulatory and administrative changes that can proceed at this time.*

4.1 Vitamins, Minerals and Amino Acids

Vitamin, mineral and amino acid products fall under the proposed definition of NHPs and will be regulated under the authority of the ONHP. However, these products are currently regulated under the *Food and Drugs Act* (the *Act*) and its regulations, which do not allow the use of the three types of health claims (structure/function, risk reduction and treatment) that will be permitted for NHPs.

In addition to the general labelling provisions of *Division 1, Part C* of the *Food and Drug Regulations* that apply to all products, further provisions relating to vitamin and mineral products are specified in *Divisions 4 and 5, Part D* of the *Regulations (Sections D.04.006, D.04.012, D.04.013, D.05.004 and D.05.005*). These provisions control health claims that may be made in advertisements and on labels for vitamin, mineral and amino acid preparations. Along with being unduly restrictive, the current regulatory provisions do not reflect the state of current scientific evidence with respect to the actions of vitamin, mineral and amino acid products.

The Transition Team recommends that:

Divisions 4 and 5, Part D of the Food and Drug Regulations be repealed and replaced by the NHP regulatory framework.

4.2 Schedule F

Some NHPs currently in *Schedule F* of the *Food and Drug Regulations* must be reconsidered under the new framework for NHPs. *Schedule F* lists those products which are required to be sold only on prescription by a qualified practitioner. De-scheduling of products from *Schedule F* requires a regulatory amendment involving public notification and consultation through the *Canada Gazette, Parts I* and *II*.

The current de-scheduling process is time consuming and inefficient. First, a review is undertaken at the bureaucratic level, recommendation for change is drafted and further consultations undertaken. A final recommendation to strike from the list is then forwarded to government and approval sought from the Minister of Health and the Special Committee of Council on Regulations (SCC). The recommendation is then published in *Canada Gazette, Part I* for a 30 to 120 day comment period, followed by analysis and re-draft for final approval by the Minister and the SCC. The government then publishes the final decision in *Canada Gazette, Part II* and, at a stipulated time following the publication, the de-scheduling becomes effective. The process can take two to three years in addition to the time required to make the actual risk-management decision.

Changes are necessary to make this process more efficient. A regulatory amendment should be unnecessary for changes to *Schedule F* for the following reasons:

a) the submission requirements and administrative processes involved in de-scheduling have already been subjected to full public consultation;
b) the determination of whether a product requires professional intervention should be an evidence-based decision requiring technical expertise and should be based on a risk-benefit assessment of the information, rather than a political decision; and,
c) the inefficiencies involved in changing *Schedule F* will force unnecessary delays in obtaining access to safe and cost effective health products while, in the interim, denying access to potentially beneficial products.

The Transition Team recommends that:

Changes to Schedule F should continue to follow the current administrative processes to ensure adequate consultation where required; however, the need for gazetting in addition to this process should be removed. Schedules should become administrative lists and scheduled products should have their conditions of sale attached to their product licenses.

4.3 Division 8

The intent of *Division 8* of *Section C* (*Food and Drug Regulations*) is to ensure the safety and effectiveness of products for which there is limited experience by requiring manufacturers to file an extensive submission prior to marketing. Manufacturers must provide substantial evidence of the clinical effectiveness of the new drug, detailed reports of the tests made to establish the safety of the new drug and specific information on the manufacturing process.

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19. NHPs be allowed to make health claims, including structure and function claims, risk-reduction claims and treatment claims.

Division 8 of the current regulations is inconsistent with the recommended regulatory framework for NHPs. For example:

a) conferring *new* product status to any product or product combination without an established Canadian history of use ignores the worldwide historical context of use;
b) post-market reporting requirements for *Division 8* products do not currently differentiate between levels of relative risk for products reclassified from higher risk to lower risk categories; and,
c) the *Division 8* definition of what constitutes a new product is too broad, capturing in its definition both new chemical entities (for which there is limited knowledge) and products which have a long history of use both in Canada under *Schedule F*, or outside Canada as lower-risk products.

The fact that *Division 8* requirements are already being dealt with administratively is a clear recognition that the definitions as stipulated in *Division 8* are too broad. For example, traditional medicines, according to the *Guideline on Traditional Herbal Medicines*

(Therapeutic Products Programme), are permitted to be marketed in Canada without reclassification as a new product, provided that marketers submit appropriate traditional references to support the products' safety and health claims. Similarly, combinations of lower-risk, traditional medicines are currently permitted in Canada without reclassification as a new product, provided that the traditional references support the use of the individual ingredients for the desired indication and that the combination is deemed rational.

The Transition Team recognizes the need to ensure that established products are not reclassified as new products upon first marketing in Canada nor subject to inappropriate pre- and post-market regulations. Regulations should be based on the relative risk of the product and should also reflect the cultural, philosophical and historical context of product usage.

The Transition Team recommends that:

Division 8 should be amended to reflect a relative risk product licensing system, as well as the cultural, philosophical and historical context of product usage.

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35. Health Canada immediately initiate a review of the diseases listed in Schedule A to ensure that only appropriate diseases are included and, where relevant, specific diseases be exempted by regulation from the broad terms found in Schedule A.

36. Health Canada, subsequently, conduct a study with the participation of representatives from consumer groups, the food, natural health products and pharmaceutical industries, and health practitioners to determine whether subsections 3(1) and (2) of the Food and Drugs Act or all of the diseases listed in Schedule A should be deleted.

4.4 Section 3 and Schedule A

Schedule A of the *Food and Drugs Act* lists a number of diseases, disorders or abnormal physical states for which treatments, preventions or cures cannot be advertised or sold to the general public. In particular, *Sections 3(1)* and *3(2)* state that:

3(1) "No person shall advertise any food, drug, cosmetic or device to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A."

3(2) "No person shall sell any food, drug, cosmetic or device
(a) that is represented by label, or
(b) that the person advertises to the general public as a treatment, preventative or cure for any of the diseases, disorders or abnormal physical states referred to in Schedule A."

Sections 3(1) and *3(2)* and *Schedule A* of the *Food and Drugs Act* are no longer relevant. They do not serve any purpose that cannot be accomplished adequately by other sections of the legislation or regulations.

More importantly, the schedule does not reflect contemporary scientific thought. The weight of modern scientific evidence confirms the mitigation and prevention of many diseases and disorders listed in Schedule A through the judicious use of NHPs. It is time that the legislation and regulations reflect the prevailing science.

Section 30(1) (m) of the *Act* grants the authority to add anything to, or delete anything from, the Schedules to the *Act*.

The Transition Team recommends that:

Section 30(1) of the Food and Drugs Act should be invoked to remove all diseases listed in Schedule A; Sections 3(1) and 3(2) should be revoked through the Legislative Renewal Initiative.

4.5 Sampling

Section 14(1) of the *Food and Drugs Act* prohibits direct-to-consumer sampling of all health products, including lower risk products. This blanket restriction is not in keeping with the risk-management model proposed for the regulation of NHPs. Sampling regulations should be based on the relative risk of the product. Lower risk NHPs are suitable for sampling to the consumer within appropriate guidelines. In fact, many lower risk products are similar in risk to cosmetics, foods or other consumer goods, which are permitted to be sampled. Current sampling regulations unduly restrict the promotion of information beneficial to the health of Canadians. An example is the promotion of good dental care through the sampling of fluoride toothpastes.

As well, the current sampling restrictions in the *Food and Drugs Act* are contradictory and confusing. The legislative definition for 'sell' includes to "distribute, whether or not the distribution is made for consideration." No definition is provided for 'sampling' but common usage implies that to sample a product to consumers is to distribute without consideration. It stands to reason that *sampling*, therefore, is a form of *selling*. Consequently, it is illogical that the current regulations prevent the sampling (selling) of a

product that has already been approved for sale in Canada. While higher risk NHPs should continue to be provided through the appropriate health professionals to mitigate potential safety concerns, there is a clear need to amend the current *Act* as it pertains to sampling of lower risk products.

The Transition Team recommends that:

current sampling restrictions should be removed from the Food and Drugs Act through the HPB Legislative Renewal Initiative. More appropriate guidelines and regulations should be drafted to reflect the relative risk of the product.

5.0 Research

5.1 Research Program

The strategy for the ONHP Research Program is to direct funding to research that is relevant to the regulatory function of the Office and sensitive to the community that produces and utilizes these products. The principles of methodological soundness and ethical peer review are key to any research program, including the ONHP Research Program.

The role of the Office is to provide leadership in the coordination of, and the networking for, NHP research in Canada by acting as a catalyst in dissemination of research results, evaluation of scientific information and stimulation of research with a focus on wellness.

The Transition Team recognizes that targeted government research funds are best seen as "seed" money for the creation of a sustainable NHP research endeavour, funded through more conventional means.

In this context, it is important to consider the strategy within the larger framework of sustainable research endeavours in Canada .[4]

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45. The federal government research bodies, including Health Canada, begin immediately to encourage research on NHPs. This could include studies focussing on the interactions of herbal products with conventional medications as well as studies that explore different uses by various groups in Canada.

46. Health Canada undertake, through its various established avenues, the dissemination of the resulting information to healthcare professionals and consumers.

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[4] Health Canada held consultations with stakeholders at The Natural Health Products Research Priority Setting Conference, Halifax, November 6-8, 1999 (report in progress). Five priorities were identified and developed during this conference, including:

a) creation of a credible and comprehensive database to facilitate a gathering and assessment of the current knowledge on NHPs;
b) conduct of risk/benefit research (including: pre-clinical animal studies; clinical studies and long-term, follow-up research in safety, effectiveness and mechanisms of action of NHPs);
c) initiation of research to aid in the development of quality control methodologies and the development of appropriate standards;
d) investigative research into traditional health economics and prevailing consumer usage; and,
e) development of new assessment methodologies to address the context of NHP usage.

The Transition Team recommends that:

the ONHP establish itself as a national repository for current NHP research that will assist in the development of future research proposals.

The Transition Team further recommends that:

the ONHP act as a disseminator of peer-reviewed published research and other reliable information to researchers, consumers and all other interested parties.

The Transition Team further recommends that:

the ONHP foster research on natural health products in the areas of safety, effectiveness, quality and health economics by acting as a catalyst in the stimulation of wellness-centered research, utilizing NHPs.

5.2 Research Incentives

Research into new claims for established products is fundamental to the continued growth of the NHPs industry and the contribution these products make to overall healthcare. The objective of increasing the level of research in this area has recently been emphasized by the Minister of Health. However, a regulatory climate which will further encourage investment in this area is required. Part of a strategy may be to provide innovative, regulatory incentives for conducting new research into uses for NHPs.

Under existing drug regulations, in many cases a manufacturer that submits proprietary research to obtain a licence for a new claim is, in reality, subsidizing its competitors. This paradox exists because, as soon as the new claim is authorized, all other competitors can implement the claim based on the data provided by the original research. Consequently, there is little incentive for companies to research NHPs.

Elsewhere, most countries are moving toward a system which protects data and related claims wherever proprietary studies are required to obtain market approval for products. The World Trade Organization is already focussed on this issue, and several countries either have provisions for claim/data protection (U. S.) or are currently developing them (Europe). The creation of the ONHP provides a unique opportunity for Canada to move forward on this issue.

The Transition Team recommends that:

the ONHP develop market incentives to encourage continued research into new claims for established products.

6.0 Communications

Guided by the ONHP Strategic Communications Framework and Plan, Health Canada formats for communication are being developed to target information, education and feedback from audiences including:

a) stakeholder groups, organizations and the general public;
b) members of the media;
c) healthcare providers (including NHP practitioners, family physicians, pharmacists and retailers of NHPs);
d) universities, hospitals and researchers;
e) Health Canada employees and other federal departments; and,
f) provincial/territorial Ministries of Health.

The Plan provides for a strategic communications approach during the implementation phase of the ONHP. It addresses a range of communications challenges and opportunities both internally, within Health Canada, and externally, involving a wide array of stakeholders.

Throughout its mandate, the Transition Team has made a consistent effort to produce public communiqués and website updates documenting its progress. Despite this, there has been a significant gap in the conveyance of such communication by Health Canada.

The Transition Team recommends that:

the Minister of Health offer visible public support and promotion of the ONHP through media activities focussing on the work of the Office as well as NHP policy and/or regulatory changes; the Minister should incorporate Health Canada's commitment to NHPs as part of all public representations on wellness.

The Transition Team further recommends that:

the ONHP should move quickly to utilize the communication tools outlined in its Strategic Communications Framework and develop a process for stakeholder consultation on proposed regulatory changes in c ncert with the new Office of Consumer Affairs and Public Involvement.

7.0 Position Statements

In the course of its work, the Transition Team has had the opportunity to bring a fresh approach to Health Canada's deliberations on a number of health-related issues. With its expertise rooted in NHPs and the holistic/wellness paradigm, the Transition Team has attempted to bring clarity and an informed perspective to salient issues, including:

a) the concept of wellness;
b) the United Nations Codex Alimentarius;
c) genetically modified organisms (GMOs);
d) the role of natural healthcare practitioners; and,
e) cultural considerations of the use of bulk herbs.

These issues are of great concern to the Canadian public, as they are to practitioners and industry stakeholders who use, recommend, supply and sell NHPs. In its public progress reports the Transition Team has articulated clear positions on these subjects to provide a definitive NHP perspective. Because these and other issues will continue to demand public response from the ONHP, the Transition Team has included the following position statements as part of its recommendations to the Minister.

7.1 Wellness – the ONHP as a Catalyst of Change

Throughout its deliberations, the Transition Team returned to the touchstone of *wellness* as an essential component of change in contemporary healthcare delivery. Lifestyle and prevention, rather than mitigation and cure, is becoming the focus as science validates the long-known healing powers of natural compounds.

7.1.1 A Paradigm Shift

Canadians today are taking firmer control over their own health and demanding greater access to products which they now recognize as central to a regimen of prevention, treatment and health optimization. Much of Canada's ethnic community, in particular our Asian and First Nations peoples, consume NHPs as a natural part of their daily diet and as an integral component of a strategy of prevention and maintenance.

A paradigm shift in healthcare is unfolding in Canada and elsewhere – one that is moving us away from the conventional, disease-centered model to a more holistic, wellness-centered model of healthcare.

Such a change presents a unique opportunity for the ONHP – an opportunity to act as a catalyst to help propel Canada toward this new, wellness-centered healthcare paradigm. Through its mandate to provide safe, effective and high quality NHPs the ONHP is, in fact, a consummate agent for such change.

The Transition Team recommends that:

the mandate of the new ONHP should be expanded to allow it to function as an effective catalyst for change toward a more holistic and pro-active, wellness-centered model of healthcare delivery in Canada. As an agent for such change, the ONHP should:

a) ***increase public awareness of the benefits of prevention, wellness and self-care;***
b) ***promote lifestyle change and the benefits of prevention, wellness and self-care, particularly among our youth and emerging adult sectors;***
c) ***promote a wellness model of healthcare delivery that accommodates and celebrates the cultural and ethnic diversity of Canada;***
d) ***encourage research that further defines the benefits of prevention, wellness and self-care with respect to health optimization and risk reduction; and,***
e) ***act as an International Ambassador for a wellness-centered model of health management.***

The Transition Team further recommends that:

the Minister of Health should become the 'Champion of the Cause' for wellness and work toward establishing Canada as a global leader in the evolution toward a more holistic, pro-active and wellness-centered, healthcare paradigm.

7.1.2 Financial Incentives

Canada's formal healthcare system is currently undergoing serious examination with a view to ensure that it is both cost effective and accessible to all Canadians. The potential impact

of prevention, wellness and self-care on the costs of delivering healthcare to citizens in all provinces is enormous. Not only does prevention and maintenance keep consumers out of the higher cost, remedial system, but the use of NHPs for the treatment of self-manageable health problems allows the remedial system to focus resources on those diseases which are best suited to professional care.

It is well known that the current system of incentives for the rational use of healthcare resources is not achieving its full objective of blending self-care and professional care. The actions which consumers take with respect to managing their own health are often influenced by the financial rewards, which the market provides. The financial aspects of the current system which influence healthcare resource utilization include: tax structures (eg. sales taxes and income tax measures), third-party payment systems for healthcare services, and products and consumer education.

The Transition Team recommends that:

the Minister of Health work with stakeholders and other government authorities to develop a comprehensive program of incentives which will promote greater use of prevention, wellness and self-care by Canadians.

7.2 Codex Alimentarius

Canada intends to regulate NHPs neither as foods nor pharmaceuticals, but as NHPs which, by both definition and regulatory authority, are now a separate category from foods. Therefore, Codex requirements for foods will have no relevance for NHPs in Canada. Consequently, Canada will need to ensure that its NHP status is secure within international agreements. This is vital, as other countries which regulate their NHPs as foods or pharmaceuticals will engage in international trade within these parameters.

The Transition recommends that:

A position paper be prepared outlining Canada's new position on NHPs for dissemination to all government officials with responsibility for international trade and relations, including Canada's Codex delegation. This briefing document should delineate the following:

a) the background leading up to the Minister's announcement of the new

ONHP and its regulatory regime;

b) ***the definition and scope of NHPs within the new regime;***
c) ***the new regulatory class of NHPs as separate from food and drugs;***
d) ***an organizational overview of the new ONHP and identification of relevant contact points;***
e) ***a summary of key initiatives to be undertaken;***
f) ***a strategic approach to facilitate the dissemination of Canada's new position on NHPs to relevant foreign officials; and,***
g) ***a strategic approach to facilitate the dissemination of Canada's position on the regulation of NHPs at the next meeting of Codex, to be convened in Bonn, Germany in June, 2000.***

7.3 Genetically Modified Organisms: Labelling

Because many NHPs and their excipients may be derivatives of foods, the issue of labelling genetically modified food products is of concern to the NHP community. Apart from the question of the long-term impact on the genetic profile of Canada's food chain is the issue of safety to the consumer. There is an increasing prevalence of GMOs throughout the Canadian domestic food chain, including their use in NHPs.

Consumers have expressed their desire to choose whether or not they will consume products which have been genetically altered or are derived from sources which have been genetically modified. This desire has also been expressed by consumers of NHPs.

It is recognized that, currently, it may not be possible to identify genetically modified organisms (GMOs) or their biochemical derivatives in the Canadian food supply. Nonetheless, in keeping with the proposed mission for the ONHP, it is believed that Canadian consumers must have the freedom to choose whether they consume GMO products or not.

The Transition Team recommends that:

consumers be allowed to make an informed choice through mandatory GMO labelling of genetically modified NHPs and excipients. In the interim, the ONHP should create a framework and develop standards to allow the labelling of non-GMO natural health products, including both active ingredients and excipients, and should liaise with other government departments and agencies to effect the

necessary changes to make this possible.

7.4 Cultural Considerations

As globalization and multiculturalism have become the norm, Canadians have come to recognize that ethnic groups form a vibrant part of our cultural tapestry. It is imperative that Canada also acknowledge and accommodate the traditions and cultural practices of its ethnic minorities with respect to their traditional healthcare practices.

The definitional guideline for natural health products (Section 3.1 of this report) acknowledges that NHPs form an integral part of the lifestyles, beliefs, habits and traditions of individuals and cultures.

Natural Health Products: A New Vision

Aboriginal Healers:

50. If a product that is extemporaneously compounded for a particular person is not exempted from the regulatory framework, that such a product be exempted.

The Transition Team recommends that:

the ONHP should be cognizant of traditional and culturally-based practices and, where circumstances require, give full consideration to, and tailor specific guidelines for, the use of culturally-based NHPs.

The Transition Team further recommends that:

the ONHP should recognize and accommodate the traditional cultural references, terminologies and concepts of ethnic minorities as part of the standards of evidence for purposes of licensing. The ONHP should also ensure proper and thorough consultation by engaging respective cultures and foreign governments as a necessary part of the ONHP's consultation process.

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47. Health Canada inform its provincial and territorial counterparts of the regulatory changes with regard to NHPs and of the concerns raised by practitioners.

7.5 Role of the Practitioner

Traditional forms of medicine and natural healthcare (NHC) practitioners have existed in Canada for many decades. These practitioners employ a diversity of NHPs in their practices. Access

to a full range of high quality NHPs is, therefore, a significant issue to both traditional practitioners and the complementary/integrative practitioners who use these products.

It is acknowledged that the regulation of healthcare practitioners is not within the purview of Health Canada. However, given the recognized inconsistences in the current provincial and territorial criteria for NHC practitioner regulation, the question of regulation is important in the context of public safety.

A new regulatory framework for NHPs must recognize the role of the traditional, natural healthcare practitioner within the context of Canada as a multicultural tapestry. Criteria that identify and regulate traditional practitioners must be developed in concert with provincial, territorial and First Nation authorities. These criteria should include the following considerations: historical origins and underpinning philosophy, traditional body of knowledge, scope of practice, traditional references and standards of evidence, educational standards, adherence to traditional philosophy and practitioner cohesiveness.

The Transition Team recommends that:

a pan-Canadian conference of federal, provincial, territorial and First Nation health representatives, and leaders and educators of the various traditional associations and teaching institutions, and practitioners, should be convened to initiate and facilitate communication and education of all stakeholders. The objectives of this process should include:

- ***a) education and sensitization of federal, provincial and territorial governments to natural healthcare (NHC) practitioners' practices and conventions;***
- ***b) education and sensitization of NHC practitioners to government regulatory and safety issues;***
- ***c) education of governments on current impediments to traditional practices;***
- ***d) implementation of joint efforts to support and better regulate the practice of traditional medicines in Canada, within the context of ensuring public safety; and,***
- ***e) publication of conference proceedings and position papers to facilitate the development of appropriate regulatory frameworks at the provincial and territorial levels.***

8.0 Summary

It is with a sense of pride and accomplishment that the Transition Team for the *Office of Natural Health Products* presents the foregoing report and recommendations to the Minister of Health. Unanimously endorsed by members of the Transition Team, the report and its recommendations are the culmination of almost ten months of exhaustive analysis and synthesis.

During the process, the Transition Team examined each of the 53 recommendations presented by the Standing Committee on Health in its landmark report *Natural Health Products: A New Vision*. The Transition Team believes that the regulatory and administrative structures proposed in this report enshrine the spirit and intent of the Standing Committee recommendations, as well as those of the original Advisory Panel on Natural Health Products.

In its deliberations, the Transition Team also developed three further recommendations dealing with the promotion of wellness. These recommendations, if adopted, would expand the mandate for the ONHP to act as a catalyst for change toward a wellness-centered, holistic healthcare paradigm. All members of the Transition Team are fervent in the belief that, in *addition* to its regulatory authority, the Office has a leading role to play, both nationally and internationally, as an 'Agent of Change' in contemporary healthcare. In this regard, the Transition Team encourages the Minister to become a 'Champion of the Cause' in this evolution toward a wellness-centered and holistic healthcare model and urges the Minister to empower the ONHP as an instrument of such change.

In consideration of this report and its recommendations, the members of the Transition Team for the *Office of Natural Health Products* have hereto set their signatures.

Appendix A
Organizational Structure

Director, Policy and Regulatory Affairs

The Director of Policy and Regulatory Affairs is accountable for conceptualizing and designing the required regulatory and policy framework for the ONHP, defining relevant policy issues and developing methodologies for policy analysis and program design. Specifically, the Director:

a) liaises with HPB legal services to establish appropriate mechanisms, timetables and action plans for policy, regulatory and legislative processes required to set up a new regulatory framework;
b) works with the EAC to develop criteria and standards for product review processes for NHP product licensing in order to maintain and enhance their safety, quality and efficacy;
c) works with the Transition Advisory Team and EAC to develop policies and regulations for inspection, investigation, enforcement, facilities licensing, and post-market surveillance activities of NHPs, and to explore the development and implementation of a fee structure for all aspects of product and facilities licensing;
d) establishes appropriate, accessible and effective appeal processes in consultation with the EAC for relevant policies and inclusion in the new regulatory and legislative framework;
e) collaborates with ONHP Outreach and Communications to consult with stakeholders on proposed changes;
f) liaises with the Therapeutic Products Programme (TPP), Food Directorate and the Canadian Food Inspection Agency (CFIA) on respective jurisdictions in order to coordinate policy and regulatory changes within the Health Protection Branch (HPB);
g) implements initial policies and legal processes for regulatory and legislative changes deemed necessary to operationalize the new NHP regulatory framework;
h) liaises with the EAC to develop ongoing policy, regulatory and legislative change;
i) informs provincial and territorial counterparts of proposed regulatory and legislative changes and promotes dialogue on provincial and territorial jurisdictional issues, such as licensing of health practitioners;
j) develops, negotiates and implements international standards and agreements as the coordinating point for international activities and represents the ONHP in international fora;
k) contributes to the development of international regulatory standards, develops partnerships with other regulatory authorities and fosters international synergy by sharing information and devising solutions; and,
l) works in collaboration with Foreign Affairs and International Trade to ensure that Canada's new regulatory definition and framework for NHPs is recognized and accommodated in relevant international agreements.

Director, Research and Program Development

The Director of Research and Program Development is accountable for developing and implementing the ONHP's strategic research agenda, identifying relevant research needs, overseeing the development of a research framework and strategy for the ONHP, evaluating the effectiveness of the research framework and directing adjustments to approaches and methodologies. Specifically, the Director:

a) conceptualizes, implements and manages a long-term research agenda to support the priorities of the ONHP and provides sound, evidence-based knowledge, intelligence and recommendations to orient policies and programs;
b) cultivates a network of experts in academia, federal research institutes and other organizations to identify ongoing research activities and gaps in current research as a basis for developing and implementing a research agenda for the ONHP;
c) identifies experts and organizations to undertake research on behalf of the ONHP;
d) consults with the Expert Advisory Committee to formulate criteria and standards for research and program development;
e) involves external academic research facilities (and other governmental, public and private sector organizations having expertise in NHPs) in experimental studies focussing on NHP interactions, safety and effectiveness, as well as studies that explore their different uses by various groups in Canada;
f) represents the ONHP in the negotiation of partnership agreements with domestic and international partners to leverage contributions of funds supporting policy research and accessing established, external knowledge bases;
g) provides advisory services to senior management on the scientific evidence identifying medium to long-term trends and developments of strategic importance to the ONHP's policies and programs;
h) works with Outreach and Communications to integrate and distribute NHP research information to stakeholders and established networks of research experts;
i) collaborates with other Directors, develops research work plans to address identified knowledge gaps and provides advice and guidance on the optimum fora and sources of information;
j) works in collaboration with the Department of Foreign Affairs and International Trade and liaises with other foreign governments to share data on research and reference materials and to attain knowledge on cultural practices relating to the consumption of NHPs; and,
k) plans and directs the effective use of assigned resources.

Director, Outreach and Communications

The Director of Outreach and Communications oversees the day-to-day information and communications needs of the ONHP and its interactions with other government agencies, stakeholders and the general public. Specifically, the Director:

a) establishes a public outreach and communications framework, develops innovative communication tools, establishes robust feedback mechanisms and recommends approaches for open and transparent communication on NHPs with stakeholders and the public (including ethnic minorities) in order to increase general awareness of ONHP services;
b) directs the ONHP Strategic Communications Plan, providing a full range of communications activities and strategies to govern internal and external communications initiatives, and positions the office to respond to ministerial and corporate priorities and objectives;
c) sets up all processes for general and Ministerial correspondence, provides authoritative advisory services and coordinates the proper response to requests for briefing notes, information sessions and ministerial inquiries;
d) links with the office of Consumer Affairs and Public Involvement, HPB Communications and other Health Canada branches to establish a private-public sector communications network with stakeholders, the public (including ethnic minorities) and other federal, provincial and territorial departments and ministries, for dissemination of information and feedback;
e) works with Policy and Regulatory Affairs to establish a consultation process among stakeholders on proposed regulatory and legislative changes;
f) directs exploratory and quantitative studies to assess the level of public awareness and need regarding information about the Office of Natural Health Products and NHPs;
g) develops long range, strategic initiatives aimed at increasing the level of public awareness for the ONHP and natural health products; and,
h) provides innovative and creative leadership and manages allocated resources to meet assigned objectives, priorities and plans.

Director, Product Regulation

The Director of Product Regulation is accountable for implementing criteria, standards and review processes for facility and product licensing and the evaluation of product safety, quality and claims.
Specifically, the Director:

a) oversees the conduct of evaluation processes related to assessment of the claims, safety, risks, benefits and availability of NHPs;
b) develops and maintains information exchange networks, collaborative ventures and consultative mechanisms with all stakeholders, including: other government departments, provincial/territorial and foreign governments, manufacturers, health care providers, pharmacists and consumers;
c) liaises with other ONHP Directors and consults with the EAC to provide feedback and input into development of new or revised policy and regulatory processes;
d) consults with the EAC in the evaluation of specific NHPs;
e) develops strategic priorities, quality assessment and monitoring frameworks for NHPs (including new GMPs, facilities and product licensing, surveillance, enforcement and monitoring) to meet Ministerial priorities and objectives, ensures consistent enforcement and provides sufficient information and interaction with industry to ensure compliance;
f) links with ONHP Policy and Regulatory Affairs and the EAC to provide feedback and input into GMP policies and inspection processes;
g) directs the implementation of a post-market monitoring system as well as an appropriate adverse event reporting system;
h) directs quality assessment and monitoring by sharing resources or contracting out services within Heath Canada in a manner that maintains the integrity of the ONHP mission;
i) maximizes the efficiency and cost effectiveness of operational activities, provides direction to all staff for assigned program areas and coordinates the implementation of policy and program initiatives across all regions;
j) identifies needs and develops training programs for field inspectors and investigators to ensure that duties are performed consistently and efficiently across the country;
k) provides advisory services to senior management related to ongoing and sensitive program issues; and,
l) manages allocated resources to meet ONHP operational plans and program activities, provides direction to staff and revises plans and activities in the light of program priorities and circumstances.

Appendix B
Interim Management Policy

Letter to the Minister of Health

January 28, 2000

The Honourable Allan Rock, PC, MP
Minister of Health
Brooke Claxton Building, 16th Floor
Postal Locator 0916-A
Ottawa, Ontario

Dear Mr. Minister:

Re - Transition Team Recommendation for NHP Interim Management Policy

The Transition Team is nearing completion of its recommendations regarding the new Office of Natural Health Products and regulatory framework. However, the Team is cognizant of the time that will be required for development of these recommendations into a comprehensive framework.

It is with a great sense of urgency that we are seeking Ministerial approval for an Interim Management Policy to be established for the regulation of natural health products. We are making this recommendation for the following reasons.

For over two years, the Health Protection Branch, the public and industry stakeholders have laboured under interim policies governing the regulation of natural health products. The effects of these policies are taking their toll:

(a) Current laws, regulations and policies do not reflect the direction and spirit of recommendations made by the Standing Committee on Health. Consequently, some current actions, including restrictive enforcement, have the effect of confusing stakeholders, the media and the public, and undermining progress in establishing the new Office of Natural Health Products and proposed regulatory change.

(b) After two years, the public, industry and all other stakeholders anxiously await evidence that Health Canada is moving forward with the new Office and regulatory framework.

The official opening of the ONHP must coincide with its assumption of authority and primary responsibility for NHPs. As well, the operations and activities of the ONHP should be conducted in partnership with other government agencies and stakeholders.

This can be accomplished with an Interim Management Policy which meets Standing Committee recommendations 42 and 43. These recommendations call for more open and transparent communication on NHPs with the broader public and practitioners, including details about decisions and actions regarding NHP products (removal from market, change of status, etc.)

Therefore, the Transition Team recommends that Health Protection Branch immediately implement an Interim Management Policy for the current regulation of Natural Health Products. This Policy would include the following:

a) That the ONHP Executive Director be the level of interim management contact and decision-making.

b) That all matters of regulatory action on NHPs (or those products deemed NHPs under the ONHP's working definition) proposed by any HPB Directorate or other branch of Health Canada, be undertaken through the Office of Natural Health Products.

c) That all regulatory decisions and actions be conducted in an open manner and reported with full explanatory communications to all stakeholders and the Canadian public in a timely fashion.

Mr. Minister, we appreciate your attention to this matter and trust that you will deal with it in an expedient manner.

Respectfully submitted on behalf
of the Transition Team

Appendix C
ONHP Transition Team

ONHP Transition Team Members

	Member	*City*	*Province*
1.	Anderson, Del	Calgary	Alberta
2.	Broughton, Colin	Scarborough	Ontario
3.	Chan, Peter	Ottawa	Ontario
4.	Chard, Sharon	Dartmouth	Nova Scotia
5.	Cheng, Lawrence	Toronto	Ontario
6.	Dugale, Valerie	Toronto	Ontario
7.	Dugas, Ronald	Aylmer	Québec
8.	Fok, Albert	Vancouver	British Columbia
9.	Herringer, Donna	Toronto	Ontario
10.	Ingles, Allan	Markham	Ontario
11.	LaValley, William	Chester	Nova Scotia
12.	MacWilliam, Lyle	Vernon	British Columbia
13.	McKeen, Claudia	Ottawa	Ontario
14.	Saunders, Paul	North York	Ontario
15.	Skinner, David	Ottawa	Ontario
16.	Vertolli, Michael	Maple	Ontario
17.	Wojewnik-Smith, Alicja	Winnipeg	Manitoba